

From: [Mayhew, James A. \(CMS/CPC\)](#)
To: [Larsen, Steven \(HHS/OCHIO\)](#)
Subject: FW: Pkg of 6 Omnibus 6.14.10 6pm
Date: Tuesday, June 15, 2010 9:13:00 AM

Here's the latest from the WH.

From: Turner, Amy - EBSA [mailto:Turner.Amy@dol.gov]
Sent: Monday, June 14, 2010 8:34 PM
To: Baum, Beth - EBSA; Butikofer, James - EBSA; Corrigan, Dara (HHS/ASPE); Cosby, Chris - EBSA; Kevin.Knopf@do.treas.gov; Kosin, Donald (HHS/OGC); Karen.B.Levin@irscounsel.treas.gov; Mayhew, James A. (CMS/CPC); russell.e.weinheimer@irscounsel.treas.gov; Schumacher, Elizabeth - EBSA; REWeinheim@aol.com; kevin.paul.knopf@gmail.com; ehschumacher@gmail.com
Subject: Re: Pkg of 6 Omnibus 6.14.10 6pm

Following up on my earlier email, below is a summary of the 5:30 call ...

General:

- a. The reg will be released June 22, on which day there will be a Presidential event.
- b. The clear message of this package and the event will be that we are providing strong consumer protections.
- c. Package is to go to OMB by cob tomorrow.
- d. I will circulate something later tonight that makes changes based on the decisions below.

Decisions:

1. The HHS opt-out reg is out of the package; it is now a 5-pack.
2. The 2714 fix is out of the package; we will find another vehicle for this later.
3. Rescission/ burden of proof issue - we will table until we can get a better legal read.
4. 30-day advance notice required for rescissions. We can add to the preamble that this gives people an opportunity to find out their rights, look for new coverage, etc.
5. Regarding prospective cancellations of coverage, we will solicit comments in the preamble on whether more guidance is needed and include a stmt about our ability to issue sub-regulatory guidance, as needed.
6. Waiver program -
 - A. The standard is an "or". That is, substantially decrease access OR substantially increase premiums.
 - B. Waiver process will be housed at HHS, even for self-insured plans.
 - C. We will delete the preamble language soliciting comments on the waiver process in advance of its implementation
 - D. The process will be up and running in Aug or Sept.
7. Restricted annual limits - we will add a good faith enforcement period for determining which benefits go in which "buckets". Because we expect most or almost all benefits to be essential health benefits, we may indicate that plans can apply a RAL to a reasonable, broad definition of benefits, at least until more guidance is issued.
8. Median - Option two. The median is determined taking into account the number of provider contracts (but not charges) at each rate.
9. RIA issues. Still evolving. The Depts will get the best draft together that they can by cob tomorrow, but it will be an initial draft that will continue to evolve over the OMB review period.

And so, we rock on! ;)

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Cc: Lynett, Elena - EBSA
Sent: Mon Jun 14 18:29:44 2010
Subject: Re: Pkg of 6 Omnibus 6.14.10 6pm

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Cc: Lynett, Elena - EBSA
Sent: Mon Jun 14 18:23:16 2010
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From: [Shaw, Adam \(CMS/CM\)](#)
To: [Mayhew, James A. \(CMS/CPC\)](#)
Subject: Pkg of 6 Reg Text 6 14 10 AMSchanges.doc
Date: Monday, June 14, 2010 10:34:03 AM
Attachments: [Pkg of 6 Reg Text 6 14 10 AMSchanges.doc](#)

Good morning.

3 substantive points (some or all of which the group may have considered.) I have added minor changes to the enclosed.

- 1) Add definition of similarly situated individual (pg. 8)
- 2) Consider adding definition of primary care provider to page 13. This is a defined term in many plans including FEHB Blue plans. It can encompass MD and non-MD (PA) and various types of MDs (internist, family doctor). Here, pediatrician must be MD or DO but PCP generally and OB/GYN does not have to be.
- 3) Consider adding reference to Newborns/Mothers mandate to pg. 15 or 16. Some of the examples deal with pre-authorization which bumps up against.

I can provide text for items 2 and/or 3 if you wish.

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** This document currently represents a single “joint” DOL/IRS/HHS reg text. The final document will actually include 3 parallel regulations – one IRS regulation (26 CFR Part 54), followed by one DOL regulation (29 CFR Part 2590), followed by one HHS regulation (45 CFR Parts 144, 146, and 147). The IRS and HHS reg texts will be re-formatted to include the correct citations for their Part. In addition, DOL and IRS will delete references to requirements for issuers of individual market coverage, but will include cross-references as appropriate.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 continues to read as follows:

Authority:

29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor’s Order 6-2009, 74 FR 21524 (May 7, 2009).

Subpart B—Other Requirements

2. Section 2590.701-2 is amended by revising the definition of preexisting condition exclusion to read as follows:

§ 2590.701-2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or

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individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

3. Section 2590.701-3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 2590.701-2 of this Part.

* * * * *

4. Section 2590.715-2704 is added to Subpart C to read as follows:

§ 2590.715-2704 Prohibition of preexisting condition exclusions.

(a) No preexisting condition exclusions—(1) In general. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701-2 of this Part).

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(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must

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comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704).

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13-year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13-year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the child is under 19 years of age and the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13-year-old child.

5. Section 2590.715-2711 is added to Subpart C to read as follows:

§2590.715-2711 No lifetime or annual limits.

(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual

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health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage,

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may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) Authority of the Secretary to grant waivers. For plan years (in the individual market, policy years) beginning before January 1, 2014, the Secretary [of Health and Human Services] may establish a program under which the requirements of this section relating to annual limits may be waived for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under this section if compliance with this section will result in a significant decrease in access to benefits under the plan or health insurance coverage or a significant increase in premiums for the plan or health insurance coverage.

(e) Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit.

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(1) In general. The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits ended under a group health plan or group or individual health insurance coverage by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a limit on the dollar value of all benefits under the group health plan or group or individual health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) Notice and enrollment opportunity requirements – (i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan – or group or individual health insurance coverage – described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual written notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The notice may be provided to an employee on behalf of the employee's dependent (in the individual market, to the primary subscriber on behalf of the primary subscriber's dependent). In addition, for a group health plan or group health insurance coverage, the notice

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may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an employee whose dependent is entitled to an enrollment opportunity under this paragraph (e), the obligation to provide the notice of enrollment opportunity under this paragraph (e)(2) with respect to that dependent is satisfied for both the plan and the issuer.

(3) Effective date of coverage. In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §2590.701-6(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals (within the meaning of §2590.702(d) of this Part) who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) Examples. The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan has a lifetime limit on the dollar value of all benefits. Individual B, an employee of Y, was enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, B incurred a claim

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for benefits that exceeded the lifetime limit under Y's plan and ceased to be enrolled in the plan. On or before January 1, 2011, Y's group health plan gives B written notice of B's right to enroll in the plan, and that B can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this paragraph (e) by providing an enrollment opportunity to C that lasts at least 30 days and written notice concerning an opportunity to enroll.

Example 2. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual D, an employee of Z, and Individual E, D's child, were enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E incurred a claim for benefits that exceeded the lifetime limit under Z's plan. D dropped family coverage but remains an employee of Z.

(ii) Conclusion. In this Example 2, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) Facts. Same facts as Example 2, except that Z's plan has two benefit packages, a high cost and a low cost benefit package. D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity (including written notice of an opportunity to enroll) to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the prohibition on lifetime limits applies to all grandfathered health plans, while the prohibition on annual limits, including the special rules regarding restricted annual limits, applies to group health plans and group health insurance coverage that are grandfathered health plans, but does not apply to individual health insurance coverage that is a grandfathered health plan).

6. Section 2590.715-2712 is added to Subpart C to read as follows:

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§ 2590.715-2712 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must **not** rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide [at least 30 days] advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

Comment [C1]: This probably has been discussed, but statute says “shall.” Why does reg. say “must?”

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual’s or group’s enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if –

- (i) The cancellation or discontinuance of coverage has only a prospective effect; or
- (ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

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(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan's terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A visited a psychologist on two occasions, six years ago. A is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's visits to the psychologist, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example 1, the plan cannot rescind A's coverage because A's failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) Facts. An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual B has coverage under the plan as a full-time employee. The employer reassigns B to a part-time position. Under the terms of the plan, B is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from B, and paying claims submitted by B. After a routine audit, the plan discovers that B no longer works at least 30 hours a week. The plan rescinds B's coverage effective as of the date that B changed from a full-time employee to a part-time employee.

(ii) Conclusion. In this Example 2, the plan cannot rescind B's coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for B prospectively, subject to other applicable Federal and State laws.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

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7. Section 2590.715-2714 is amended by revising paragraphs (d) and (h) to read as follows:

(d) Uniformity irrespective of age.—(1) In general. Subject to paragraph (d)(2) of this section, the terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(2) Preexisting condition exclusions for children age 19 and older before 2014. For plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or health insurance coverage may impose a preexisting condition exclusion (consistent with the rules of section 2590.701-3 of this Part [HHS add: “in the group market”]) on children who are age 19 or older even though this is prohibited with respect to children under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

8. Section 2590.715-2716 is added to Subpart C to read as follows:

§ 2590.715-2716 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code (prohibiting discrimination in favor of highly compensated individuals under a self-insured medical expense reimbursement plan as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-

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insured plan) under this section as if the group health plan were a self-insured medical expense reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the rules prohibiting discrimination in favor of highly compensated individuals by insured group health plans do not apply to grandfathered health plans).

9. Section 2590.715-2719A is added to Subpart C to read as follows:

§ 2590.715-2719A Patient protections.

(a) Choice of health care professional – (1) Designation of primary care provider—(i) In general. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) Example. The rules of this paragraph (a)(1) are illustrated by the following example:

Comment [C2]: Primary care provider is a defined term in FEHBP to make the point that it can be internist, family doctor, GP, as well as non-physician (PA). Consider adding that. Pediatrician has to be an MD or DO, Ob/gyn doesn't. So 2 out of 3 situations here allow non-physician.

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Example. (i) Facts. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any participating primary care provider who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) Conclusion. In this Example, the plan has satisfied the requirements of paragraph (a) of this section.

(2) Designation of pediatrician as primary care provider—(i) In general. If a group health plan or health insurance issuer offering group or individual health insurance coverage requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) Construction. Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) Examples. The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An HMO designates for each enrollee a physician who specializes in internal medicine to serve as the primary care provider for the enrollee and the enrollee's family. Enrollee A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

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(ii) Conclusion. In this Example 1, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) Facts. Same facts as Example 1, except that A takes A's child to B for treatment of the child's severe peanut allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access. A group health plan or health insurance issuer offering group or individual health insurance coverage described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) in writing that the plan or issuer may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care, and is not limited to a physician.

Comment [C3]: Some of this potentially bumps up against Newborn and Mothers. If the group hasn't already, consider note that this not meant to limit protections under Newborn and Mothers.

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(B) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of ~~a the~~ primary care provider.

(ii) Application of paragraph. A group health plan or health insurance issuer offering group or individual health insurance coverage is described in this paragraph if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) Construction. Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) Examples. The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

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(ii) Conclusion. In this Example 1, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) Facts. Same facts as Example 1 except that A seeks gynecological services from C, an out-of-network provider.

(ii) Conclusion. In this Example 2, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) Facts. Same facts as Example 1 except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(ii) Conclusion. In this Example 3, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for a scheduled cesarean section.

(ii) Conclusion. In this Example 4, the plan requirement for prior authorization before providing benefits for a scheduled cesarean section does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to services for treatments, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) Notice of right to designate a primary care provider. (i) In general. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights –

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

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(B) Under paragraph (a)(2)(i) of this section, that any participating physician who specializes in pediatrics as the child's primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) Timing. In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) Model language. The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

Because [name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider, you have the right to designate any primary care provider who participates in the network of [name of plan or coverage] and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the plan administrator at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, insert:

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If you have a child who is enrolled in [name of group health plan or health insurance issuer], you have the right to designate any pediatrician who participates in the network of [plan or coverage] and who is available to accept your child as your child's primary care provider. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one.] For information on how to select a pediatrician, and for a list of the participating pediatricians, contact the plan administrator at [insert contact information].

(C) For plans and issuers that provide coverage for **obstetrical** or gynecological care and require the designation by a participant, beneficiary or enrollee of a primary care provider, insert:

Comment [C4]: If you are using obstetrical to follow the statute, need this change. Not sure obstetrical is a word.

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain obstetrical or gynecological care from a health care professional who specializes in obstetrics or gynecology and who participates in the network of [name of group health plan or issuer]. Such a health care professional, however, may be required to comply with certain procedures required by [name of group health plan or issuer] including obtaining prior authorization for certain services, following a pre-approved treatment plan, or for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the plan administrator at [insert contact information].

(b) Coverage of emergency services.—(1) Scope. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) General rules. A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner –

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

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(iii) If the emergency services are provided out-of-network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

Comment [C5]: Is non-hyphenation intentional?

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than –

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code; or

(C) Applicable ~~cost-cost-~~sharing.

(3) Cost-sharing requirements – (i) Copayments and coinsurance. Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

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(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is [the median of these amounts irrespective of the number of providers charging][the median of these amounts, ranking them by the number of providers with which the rates were negotiated], excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) Other cost-sharing. Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits.

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If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) Examples. The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to services in an emergency department of a hospital.

Example 1. (i) Facts. A group health plan imposes a 25 percent coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual provides notice to the plan within two business days after the day an individual receives screening or treatment in an emergency department, the plan reduces the coinsurance rate to 15 percent.

(ii) Conclusion. In this Example 1, the requirement to provide notice in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required notice before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a \$60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) Conclusion. In this Example 2, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it receive notification rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) Facts. A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers there are five amounts: \$85, \$100, \$110, \$120, and \$150. Under the agreement, the plan agrees to pay the providers 80 percent of the agreed amount, with the individual receiving the service responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 3, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$110 (\$88).

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Example 4. (i) Facts. Same facts as Example 3. Subsequently, the plan adds a provider to its network and agrees to pay the provider 80 percent of \$170 for the emergency service, with the individual responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 4, the median amount among those agreed to for the emergency service is \$115. (Because there is no one middle amount among \$85, \$100, \$110, \$120, \$150, and \$170, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$115 (\$92).

Example 5. (i) Facts. Same facts as Example 4. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50 percent of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is \$116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, ~~is would be~~ \$80.

(ii) Conclusion. In this Example 5, the plan is responsible for paying \$92.80; ~~(80 percent of \$116.)~~ The median amount among those agreed to for the emergency service is \$115 and the amount the plan would pay is \$92 (80 percent of \$115); the amount calculated using the same method the plan uses to determine payments for out-of-network services -- \$116 -- excluding the in-network 20 percent coinsurance, is \$92.80; and the Medicare payment is \$80. Thus, the greatest amount is \$92.80. The individual is responsible for the remaining \$32.20 charged by the out-of-network provider.

Example 6. (i) Facts. Same facts as Example 5. The group health plan generally imposes a \$250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of network.

(ii) Conclusion. In this Example 6, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network.

(4) Definitions. The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe

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pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions, and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) Emergency services. The term emergency services means, with respect to an emergency medical condition –

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) Stabilize. The term to stabilize, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered

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health plans (providing that these rules regarding patient protections do not apply to all grandfathered health plans).

10. Section 146.180 is amended as follows:

- A. Revising paragraph (a)(1).
- B. Adding a new paragraph (a)(2).
- C. Renumbering paragraphs (a)(2), (a)(3) and (a)(4) as (a)(3), (a)(4) and (a)(5), respectively.
- D. Replacing “2706” with “2727” each place it appears in paragraph (a)(1)(i)(F) and in Example 1 of paragraph (a)(3) (previously designated as (a)(2)).
- E. Making a conforming change to paragraph (a)(4)(i) (previously designated as (a)(3)(i)).
- F. Updating paragraph (c) to reflect the current address to which exemption elections may be mailed and providing a facsimile number to which elections may be faxed as an alternative to mailing elections.
- G. Removing the outdated parenthetical reference to § 146.125(a)(2) in paragraph (f)(2)(ii).
- H. Making a conforming change to paragraph (f)(3)(i).
- I. Adding a conforming sentence at the end of Example 1 in paragraph (h)(4)(i).
- J. Updating Example 4 in paragraph (i)(2)(iv).

The revisions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) Requirements subject to exemption—(1) Non-collectively bargained plans. (i) Plan years commencing before September 23, 2010. A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), for plan years commencing before September 23, 2010, from any or all of the following requirements:

- (A) Limitations on preexisting condition exclusion periods described in § 146.111.
- (B) Special enrollment periods for individuals and dependents described in § 146.117.

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(C) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements in § 146.121(a)(1)(vi) and § 146.122 that prohibit discrimination with respect to genetic information.

(D) Standards relating to benefits for mothers and newborns described in § 146.130.

(E) Parity in the application of certain limits to mental health and substance use disorder benefits described in § 146.136.

(F) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2727 of the PHS Act.

(G) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(ii) Plan years beginning on or after September 23, 2010. A sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan for plan years beginning on or after September 23, 2010, only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) or (G). With respect to those plan years, the notices required by paragraph (f) of this section must reflect the limitations set forth in this paragraph (a)(1)(ii).

(iii) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1)(i). The plan year commences September 1 each year. The plan is not subject to the limitations of paragraph (a)(1)(ii) until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

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(iv) Example 2. Same facts as in Example 1, except the plan year commences October 1 each year. The plan is subject to the limitations of paragraph (a)(1)(ii) beginning with the plan year that commences on October 1, 2010. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(2) Collectively bargained plans. (i) Special rule. Without regard to paragraph (b)(2) of this section, a group health plan that is governed by a collective bargaining agreement that was ratified before March 23, 2010, is subject to the limitations set forth in paragraph (a)(1)(ii) beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement. The notices required by paragraph (f) of this section, with respect to the first plan year subject to the limitations of paragraph (a)(1)(ii), must reflect those limitations.

(ii) Example. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1)(i) of this section. The collective bargaining agreement applies to five plan years, October 1, 2007 through September 30, 2012. For the plan year that commences on October 1, 2012, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1)(i)(A), (B) and (C). Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(3) Limitations. * * *

(A) Example 1. A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must

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cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

* * *

(4) Stop-loss or excess risk coverage. For purposes of this section—(i) Subject to paragraph (a)(4)(ii), * * *

(5) Construction. * * *

* * * * *

(c) Mailing address. The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Medicare Enrollment and Appeals Group, CM, ATTN: HIPAA Opt-Out, 7500 Security Boulevard, C2-12-16, Baltimore, MD 21244-1850. Alternatively, the plan sponsor may fax the exemption election to 410-786-8001.

* * * * *

(f) * * *

(2) * * *

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, * * *

(3) * * *

(i) The specific requirements described in paragraphs (a)(1) or (a)(2) of this section, as applicable, from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

* * * * *

(h) * * *

(4) * * *

(i) Example 1. (A) * * *

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(B) * * * However, regarding plan years that begin on or after September 23, 2010, the plan sponsor no longer can elect to exempt its plan from prohibitions against enrollment discrimination based on health status-related factors.

* * *

(i) * * *

(2) * * *

(iv) Example 4: A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from the requirements of paragraph (a)(1)(i)(E) of this section.

The collective bargaining agreement applies to five plan years, 2007 through 2011. For the first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2007 through December 31, 2011. Prior to the dissemination of the annual notice for the 2010 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2007 through December 31, 2011. Accordingly, CMS would not invalidate the election for the 2010 plan year.

* * * * *

From: [Mayhew, James A. \(CMS/CPC\)](#)
To: ["Baum, Beth - EBSA"](#); [Corrigan, Dara \(HHS/OHR\)](#); [Kosin, Donald \(HHS/OGC\)](#); [Dailey, Joan \(HHS/OGC\)](#); [Stafford, Leslie \(HHS/OGC\)](#); ["Weinheimer Russell E"](#); ["Knopf Kevin - OTP"](#); ["Russ Weinheimer - HOME"](#); ["Kevin Knopf - HOME"](#); ["Levin Karen"](#); ["Schumacher, Elizabeth - EBSA"](#); ["Turner, Amy - EBSA"](#)
Subject: RE: Clean Drafts
Date: Sunday, June 13, 2010 11:58:00 AM
Attachments: [Pkg of 6 Reg Text 6 13 10.HHS version.doc](#)

Here is the HHS version of the regulation text.

-----Original Message-----

From: Baum, Beth - EBSA [<mailto:baum.beth@dol.gov>]

Sent: Friday, June 11, 2010 6:20 PM

To: Corrigan, Dara (HHS/ASPE); Mayhew, James A. (CMS/CPC); Kosin, Donald (HHS/OGC); Dailey, Joan (HHS/OGC); Stafford, Leslie (HHS/OGC); Weinheimer Russell E; Knopf Kevin - OTP; Russ Weinheimer - HOME; Kevin Knopf - HOME; Levin Karen; Schumacher, Elizabeth - EBSA; Baum, Beth - EBSA; Turner, Amy - EBSA

Subject: Clean Drafts

This is what we are going to circulate internally for comment over the weekend.

The plan is to meet at 11am to start incorporating comments and send to OMB by COB Monday.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

45 CFR Subtitle A

45 CFR Part 144 is amended by revising in section 144.103 the definition of preexisting condition exclusion to read as follows:

§ 144.103 Definitions.

* * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * *

Part 146 is amended as follows:

1. 146.111(a)(1)(i) is revised to read as follows:

§ 146.111 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 144.103 of this Part.

* * * * *

2. Section 146.180 is amended as follows:

- A. Revising paragraph (a)(1).
- B. Adding a new paragraph (a)(2).
- C. Renumbering paragraphs (a)(2), (a)(3) and (a)(4) as (a)(3), (a)(4) and (a)(5), respectively.
- D. Replacing “2706” with “2727” each place it appears in paragraph (a)(1)(i)(F) and in Example 1 of paragraph (a)(3) (previously designated as (a)(2)).
- E. Making a conforming change to paragraph (a)(4)(i) (previously designated as (a)(3)(i)).
- F. Updating paragraph (c) to reflect the current address to which exemption elections may be mailed and providing a facsimile number to which elections may be faxed as an alternative to mailing elections.
- G. Removing the outdated parenthetical reference to § 146.125(a)(2) in paragraph (f)(2)(ii).
- H. Making a conforming change to paragraph (f)(3)(i).
- I. Adding a conforming sentence at the end of Example 1 in paragraph (h)(4)(i).
- J. Updating Example 4 in paragraph (i)(2)(iv).

The revisions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) Requirements subject to exemption—(1) Non-collectively bargained plans. (i) Plan years commencing before September 23, 2010. A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance

coverage, (that is, it is self-funded), for plan years commencing before September 23, 2010, from any or all of the following requirements:

(A) Limitations on preexisting condition exclusion periods described in § 146.111.

(B) Special enrollment periods for individuals and dependents described in § 146.117.

(C) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements in § 146.121(a)(1)(vi) and § 146.122 that prohibit discrimination with respect to genetic information.

(D) Standards relating to benefits for mothers and newborns described in § 146.130.

(E) Parity in the application of certain limits to mental health and substance use disorder benefits described in § 146.136.

(F) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2727 of the PHS Act.

(G) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(ii) Plan years beginning on or after September 23, 2010. A sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan for plan years beginning on or after September 23, 2010, only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) or (G). With respect to those plan years, the notices required by paragraph (f) of this section must reflect the limitations set forth in this paragraph (a)(1)(ii).

(iii) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1)(i). The plan year commences September 1 each year. The plan is not subject to the limitations of paragraph

(a)(1)(ii) until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(iv) Example 2. Same facts as in Example 1, except the plan year commences October 1 each year. The plan is subject to the limitations of paragraph (a)(1)(ii) beginning with the plan year that commences on October 1, 2010. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(2) Collectively bargained plans. (i) Special rule. Without regard to paragraph (b)(2) of this section, a group health plan that is governed by a collective bargaining agreement that was ratified before March 23, 2010, is subject to the limitations set forth in paragraph (a)(1)(ii) beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement. The notices required by paragraph (f) of this section, with respect to the first plan year subject to the limitations of paragraph (a)(1)(ii), must reflect those limitations.

(ii) Example. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1)(i) of this section. The collective bargaining agreement applies to five plan years, October 1, 2007 through September 30, 2012. For the plan year that commences on October 1, 2012, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1)(i)(A), (B) and (C). Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(3) Limitations. * * *

(A) Example 1. A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

* * *

(4) Stop-loss or excess risk coverage. For purposes of this section—(i) Subject to paragraph (a)(4)(ii), * * *

(5) Construction. * * *

* * * * *

(c) Mailing address. The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Medicare Enrollment and Appeals Group, CM, ATTN: HIPAA Opt-Out, 7500 Security Boulevard, C2-12-16, Baltimore, MD 21244-1850. Alternatively, the plan sponsor may fax the exemption election to 410-786-8001.

* * * * *

(f) * * *

(2) * * *

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, * * *

(3) * * *

(i) The specific requirements described in paragraphs (a)(1) or (a)(2) of this section, as applicable, from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

* * * * *

(h) * * *

(4) * * *

(i) Example 1. (A) * * *

(B) * * * However, regarding plan years that begin on or after September 23, 2010, the plan sponsor no longer can elect to exempt its plan from prohibitions against enrollment discrimination based on health status-related factors.

* * *

(i) * * *

(2) * * *

(iv) Example 4: A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from the requirements of paragraph (a)(1)(i)(E) of this section. The collective bargaining agreement applies to five plan years, 2007 through 2011. For the first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2007 through December 31, 2011. Prior to the dissemination of the annual notice for the 2010 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2007 through December 31, 2011. Accordingly, CMS would not invalidate the election for the 2010 plan year.

* * * * *

Part 147 is amended as follows:

1. Sections 147.108, 147.126, 147.128, 147.132, and 147.138 are added to read as follows:

§ 147.108 Prohibition of preexisting condition exclusions.

(a) No preexisting condition exclusions—(1) In general. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 144.103 of this Part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must

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comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704).

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13-year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13-year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the child is under 19 years of age and the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13-year-old child.

§147.126 No lifetime or annual limits.

(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual

health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage,

may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) Authority of the Secretary to grant waivers. For plan years (in the individual market, policy years) beginning before January 1, 2014, the Secretary [of Health and Human Services] may establish a program under which the requirements of this section relating to annual limits may be waived for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under this section if compliance with this section will result in a significant decrease in access to benefits under the plan or health insurance coverage or a significant increase in premiums for the plan or health insurance coverage.

(e) Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit.

(1) In general. The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits ended under a group health plan or group or individual health insurance coverage by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a limit on the dollar value of all benefits under the group health plan or group or individual health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) Notice and enrollment opportunity requirements – (i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan – or group or individual health insurance coverage – described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The notice may be provided to an employee on behalf of the employee's dependent (in the individual market, to the primary subscriber on behalf of the primary subscriber's dependent). In addition, for a group health plan or group health insurance coverage, the notice

may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an employee whose dependent is entitled to an enrollment opportunity under this paragraph (e), the obligation to provide the notice of enrollment opportunity under this paragraph (e)(2) with respect to that dependent is satisfied for both the plan and the issuer.

(3) Effective date of coverage. In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §146.117(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) Examples. The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan has a lifetime limit on the dollar value of all benefits. Individual B, an employee of Y, was enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, B incurred a claim

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for benefits that exceeded the lifetime limit under Y's plan and ceased to be enrolled in the plan. On or before January 1, 2011, Y's group health plan gives B written notice of B's right to enroll in the plan, and that B can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this paragraph (e) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual D, an employee of Z, and Individual E, D's child, were enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E incurred a claim for benefits that exceeded the lifetime limit under Z's plan. D dropped family coverage but remains an employee of Z.

(ii) Conclusion. In this Example 2, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) Facts. Same facts as Example 2, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that the prohibition on lifetime limits applies to all grandfathered health plans, while the prohibition on annual limits, including the special rules regarding restricted annual limits, applies to group health plans and group health insurance coverage that are grandfathered health plans, but do not apply to individual health insurance coverage that is a grandfathered health plan).

§ 147.128 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide [at least 30 days] advance notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if –

(i) The cancellation or discontinuance of coverage has only a prospective effect; or

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

(3) The rules of this paragraph (a) are illustrated by the following examples:

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Example 1. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A visited a psychologist on two occasions, six years ago. A is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's visits to the psychologist, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example 1, the plan cannot rescind A's coverage because A's failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) Facts. An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual B has coverage under the plan as a full-time employee. The employer reassigns B to a part-time position. Under the terms of the plan, B is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from B, and paying claims submitted by B. After a routine audit, the plan discovers that B no longer works at least 30 hours a week. The plan rescinds B's coverage effective as of the date that B changed from a full-time employee to a part-time employee.

(ii) Conclusion. In this Example 2, the plan cannot rescind B's coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for B prospectively, subject to other applicable Federal and State laws.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

§ 147.132 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code (prohibiting discrimination in favor of highly compensated individuals under a self-insured medical expense reimbursement plan as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-insured plan) under this section as if the group health plan were a self-insured medical expense reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that the rules prohibiting discrimination in favor of highly compensated individuals by insured group health plans do not apply to grandfathered health plans).

§ 147.138 Patient protections.

(a) Choice of health care professional – (1) Designation of primary care provider—(i) In general. If a group health plan, or a health insurance issuer offering group or individual health

insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) Example. The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) Facts. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any participating primary care provider who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) Conclusion. In this Example, the plan has satisfied the requirements of paragraph (a) of this section.

(2) Designation of pediatrician as primary care provider—(i) In general. If a group health plan or health insurance issuer offering group or individual health insurance coverage requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) Construction. Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) Examples. The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An HMO designates for each enrollee a physician who specializes in internal medicine to serve as the primary care provider for the enrollee and the enrollee's family. Enrollee A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

(ii) Conclusion. In this Example 1, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) Facts. Same facts as Example 1, except that A takes A's child to B for treatment of the child's severe peanut allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access. A group health plan or health insurance issuer offering group or individual health insurance coverage described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a

participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care and is not limited to a physician.

(B) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) Application of paragraph. A group health plan or health insurance issuer offering group or individual health insurance coverage is described in this paragraph if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) Construction. Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) Examples. The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(ii) Conclusion. In this Example 1, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) Facts. Same facts as Example 1 except that A seeks gynecological services from C, an out-of-network provider.

(ii) Conclusion. In this Example 2, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) Facts. Same facts as Example 1 except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(ii) Conclusion. In this Example 3, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for a scheduled cesarean section.

(ii) Conclusion. In this Example 4, the plan requirement for prior authorization before providing benefits for a scheduled cesarean section does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to services for treatments, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) Notice of right to designate a primary care provider. (i) In general. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights –

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, that any participating physician who specializes in pediatrics as the child's primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) Timing. In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) Model language. The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

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Because [name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider, you have the right to designate any primary care provider who participates in the network of [name of plan or coverage] and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the plan administrator at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, insert:

If you have a child who is enrolled in [name of group health plan or health insurance issuer], you have the right to designate any pediatrician who participates in the network of [plan or coverage] and who is available to accept your child as your child's primary care provider. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one.] For information on how to select a pediatrician, and for a list of the participating pediatricians, contact the plan administrator at [insert contact information].

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary or enrollee of a primary care provider, insert:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain obstetrical or gynecological care from a health care professional who specializes in obstetrics or gynecology and who participates in the network of [name of group health plan or issuer]. Such a health care professional, however, may be required to comply with certain procedures required by [name of group health plan or issuer] including obtaining prior authorization for certain services, following a pre-approved treatment plan, or for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the plan administrator at [insert contact information].

(b) Coverage of emergency services.—(1) Scope. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) General rules. A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner –

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than –

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code; or

(C) Applicable cost sharing.

(3) Cost-sharing requirements – (i) Copayments and coinsurance. Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this

paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is [the median of these amounts irrespective of the number of providers charging][the median of these amounts, ranking them by the number of providers with which the rates were negotiated], excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) Other cost sharing. Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) Examples. The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to services in an emergency department of a hospital.

Example 1. (i) Facts. A group health plan imposes a 25 percent coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual provides notice to the plan within two business days after the day an individual receives screening or treatment in an emergency department, the plan reduces the coinsurance rate to 15 percent.

(ii) Conclusion. In this Example 1, the requirement to provide notice in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required notice before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a \$60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) Conclusion. In this Example 2, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it receive notification rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) Facts. A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service.

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Each provider has agreed to provide the service for a certain amount. Among all the providers there are five amounts: \$85, \$100, \$110, \$120, and \$150. Under the agreement, the plan agrees to pay the providers 80 percent of the agreed amount, with the individual receiving the service responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 3, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$110 (\$88).

Example 4. (i) Facts. Same facts as Example 3. Subsequently, the plan adds a provider to its network and agrees to pay the provider 80 percent of \$170 for the emergency service, with the individual responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 4, the median amount among those agreed to for the emergency service is \$115. (Because there is no one middle amount among \$85, \$100, \$110, \$120, \$150, and \$170, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$115 (\$92).

Example 5. (i) Facts. Same facts as Example 4. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50 percent of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is \$116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, would be \$80.

(ii) Conclusion. In this Example 5, the plan is responsible for paying \$92.80, 80 percent of \$116. The median amount among those agreed to for the emergency service is \$115 and the amount the plan would pay is \$92 (80 percent of \$115); the amount calculated using the same method the plan uses to determine payments for out-of-network services -- \$116 -- excluding the in-network 20 percent coinsurance, is \$92.80; and the Medicare payment is \$80. Thus, the greatest amount is \$92.80. The individual is responsible for the remaining \$32.20 charged by the out-of-network provider.

Example 6. (i) Facts. Same facts as Example 5. The group health plan generally imposes a \$250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of network.

(ii) Conclusion. In this Example 6, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered

individual has not satisfied the higher deductible that applies generally to all health care provided out of network.

(4) Definitions. The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions, and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) Emergency services. The term emergency services means, with respect to an emergency medical condition –

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) Stabilize. The term to stabilize, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to all grandfathered health plans).

2. Section 147.120 is amended by revising paragraph (d) to read as follows:

(d) Uniformity irrespective of age.—(1) In general. Subject to paragraph (d)(2) of this section, the terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(2) Preexisting condition exclusions for children age 19 and older before 2014. For plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or health insurance coverage may impose a preexisting condition exclusion (in the group market, consistent with the rules of section 146.111 of this Part) on children who are age 19 or older even though this is prohibited with respect to children under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

45 CFR Subtitle A

45 CFR Part 144 is amended by revising in section 144.103 the definition of preexisting condition exclusion to read as follows:

§ 144.103 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

Part 146 is amended as follows:

1. 146.111(a)(1)(i) is revised to read as follows:

§ 146.111 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 144.103 of this Part.

* * * * *

2. Section 146.180 is amended as follows:

- A. Revising paragraph (a)(1).
- B. Adding a new paragraph (a)(2).
- C. Renumbering paragraphs (a)(2), (a)(3) and (a)(4) as (a)(3), (a)(4) and (a)(5), respectively.
- D. Replacing “2706” with “2727” each place it appears in paragraph (a)(1)(i)(F) and in Example 1 of paragraph (a)(3) (previously designated as (a)(2)).
- E. Making a conforming change to paragraph (a)(4)(i) (previously designated as (a)(3)(i)).
- F. Updating paragraph (c) to reflect the current address to which exemption elections may be mailed and providing a facsimile number to which elections may be faxed as an alternative to mailing elections.
- G. Removing the outdated parenthetical reference to § 146.125(a)(2) in paragraph (f)(2)(ii).
- H. Making a conforming change to paragraph (f)(3)(i).
- I. Adding a conforming sentence at the end of Example 1 in paragraph (h)(4)(i).
- J. Updating Example 4 in paragraph (i)(2)(iv).

The revisions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) Requirements subject to exemption—(1) Non-collectively bargained plans. (i) Plan years commencing before September 23, 2010. A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance

coverage, (that is, it is self-funded), for plan years commencing before September 23, 2010, from any or all of the following requirements:

(A) Limitations on preexisting condition exclusion periods described in § 146.111.

(B) Special enrollment periods for individuals and dependents described in § 146.117.

(C) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements in § 146.121(a)(1)(vi) and § 146.122 that prohibit discrimination with respect to genetic information.

(D) Standards relating to benefits for mothers and newborns described in § 146.130.

(E) Parity in the application of certain limits to mental health and substance use disorder benefits described in § 146.136.

(F) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2727 of the PHS Act.

(G) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(ii) Plan years beginning on or after September 23, 2010. A sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan for plan years beginning on or after September 23, 2010, only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) or (G). With respect to those plan years, the notices required by paragraph (f) of this section must reflect the limitations set forth in this paragraph (a)(1)(ii).

(iii) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1)(i). The plan year commences September 1 each year. The plan is not subject to the limitations of paragraph

(a)(1)(ii) until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(iv) Example 2. Same facts as in Example 1, except the plan year commences October 1 each year. The plan is subject to the limitations of paragraph (a)(1)(ii) beginning with the plan year that commences on October 1, 2010. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(2) Collectively bargained plans. (i) Special rule. Without regard to paragraph (b)(2) of this section, a group health plan that is governed by a collective bargaining agreement that was ratified before March 23, 2010, is subject to the limitations set forth in paragraph (a)(1)(ii) beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement. The notices required by paragraph (f) of this section, with respect to the first plan year subject to the limitations of paragraph (a)(1)(ii), must reflect those limitations.

(ii) Example. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1)(i) of this section. The collective bargaining agreement applies to five plan years, October 1, 2007 through September 30, 2012. For the plan year that commences on October 1, 2012, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1)(i)(A), (B) and (C). Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(3) Limitations. * * *

(A) Example 1. A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

* * *

(4) Stop-loss or excess risk coverage. For purposes of this section—(i) Subject to paragraph (a)(4)(ii), * * *

(5) Construction. * * *

* * * * *

(c) Mailing address. The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Medicare Enrollment and Appeals Group, CM, ATTN: HIPAA Opt-Out, 7500 Security Boulevard, C2-12-16, Baltimore, MD 21244-1850. Alternatively, the plan sponsor may fax the exemption election to 410-786-8001.

* * * * *

(f) * * *

(2) * * *

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, * * *

(3) * * *

(i) The specific requirements described in paragraphs (a)(1) or (a)(2) of this section, as applicable, from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

* * * * *

(h) * * *

(4) * * *

(i) Example 1. (A) * * *

(B) * * * However, regarding plan years that begin on or after September 23, 2010, the plan sponsor no longer can elect to exempt its plan from prohibitions against enrollment discrimination based on health status-related factors.

* * *

(i) * * *

(2) * * *

(iv) Example 4: A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from the requirements of paragraph (a)(1)(i)(E) of this section. The collective bargaining agreement applies to five plan years, 2007 through 2011. For the first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2007 through December 31, 2011. Prior to the dissemination of the annual notice for the 2010 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2007 through December 31, 2011. Accordingly, CMS would not invalidate the election for the 2010 plan year.

* * * * *

Part 147 is amended as follows:

1. Sections 147.108, 147.126, 147.128, 147.132, and 147.138 are added to read as follows:

§ 147.108 Prohibition of preexisting condition exclusions.

(a) No preexisting condition exclusions—(1) In general. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 144.103 of this Part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must

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comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704).

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13-year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13-year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the child is under 19 years of age and the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13-year-old child.

§147.126 No lifetime or annual limits.

(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual

health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage,

may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) Authority of the Secretary to grant waivers. For plan years (in the individual market, policy years) beginning before January 1, 2014, the Secretary [of Health and Human Services] may establish a program under which the requirements of this section relating to annual limits may be waived for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under this section if compliance with this section will result in a significant decrease in access to benefits under the plan or health insurance coverage or a significant increase in premiums for the plan or health insurance coverage.

(e) Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit.

(1) In general. The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits ended under a group health plan or group or individual health insurance coverage by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a limit on the dollar value of all benefits under the group health plan or group or individual health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) Notice and enrollment opportunity requirements – (i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan – or group or individual health insurance coverage – described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The notice may be provided to an employee on behalf of the employee's dependent (in the individual market, to the primary subscriber on behalf of the primary subscriber's dependent). In addition, for a group health plan or group health insurance coverage, the notice

may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an employee whose dependent is entitled to an enrollment opportunity under this paragraph (e), the obligation to provide the notice of enrollment opportunity under this paragraph (e)(2) with respect to that dependent is satisfied for both the plan and the issuer.

(3) Effective date of coverage. In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §146.117(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) Examples. The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan has a lifetime limit on the dollar value of all benefits. Individual B, an employee of Y, was enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, B incurred a claim

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for benefits that exceeded the lifetime limit under Y's plan and ceased to be enrolled in the plan. On or before January 1, 2011, Y's group health plan gives B written notice of B's right to enroll in the plan, and that B can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this paragraph (e) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual D, an employee of Z, and Individual E, D's child, were enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E incurred a claim for benefits that exceeded the lifetime limit under Z's plan. D dropped family coverage but remains an employee of Z.

(ii) Conclusion. In this Example 2, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) Facts. Same facts as Example 2, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that the prohibition on lifetime limits applies to all grandfathered health plans, while the prohibition on annual limits, including the special rules regarding restricted annual limits, applies to group health plans and group health insurance coverage that are grandfathered health plans, but do not apply to individual health insurance coverage that is a grandfathered health plan).

§ 147.128 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide [at least 30 days] advance notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if –

(i) The cancellation or discontinuance of coverage has only a prospective effect; or

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

(3) The rules of this paragraph (a) are illustrated by the following examples:

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Example 1. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A visited a psychologist on two occasions, six years ago. A is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's visits to the psychologist, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example 1, the plan cannot rescind A's coverage because A's failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) Facts. An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual B has coverage under the plan as a full-time employee. The employer reassigns B to a part-time position. Under the terms of the plan, B is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from B, and paying claims submitted by B. After a routine audit, the plan discovers that B no longer works at least 30 hours a week. The plan rescinds B's coverage effective as of the date that B changed from a full-time employee to a part-time employee.

(ii) Conclusion. In this Example 2, the plan cannot rescind B's coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for B prospectively, subject to other applicable Federal and State laws.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

§ 147.132 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code (prohibiting discrimination in favor of highly compensated individuals under a self-insured medical expense reimbursement plan as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-insured plan) under this section as if the group health plan were a self-insured medical expense reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that the rules prohibiting discrimination in favor of highly compensated individuals by insured group health plans do not apply to grandfathered health plans).

§ 147.138 Patient protections.

(a) Choice of health care professional – (1) Designation of primary care provider—(i) In general. If a group health plan, or a health insurance issuer offering group or individual health

insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) Example. The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) Facts. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any participating primary care provider who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) Conclusion. In this Example, the plan has satisfied the requirements of paragraph (a) of this section.

(2) Designation of pediatrician as primary care provider—(i) In general. If a group health plan or health insurance issuer offering group or individual health insurance coverage requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) Construction. Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) Examples. The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An HMO designates for each enrollee a physician who specializes in internal medicine to serve as the primary care provider for the enrollee and the enrollee's family. Enrollee A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

(ii) Conclusion. In this Example 1, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) Facts. Same facts as Example 1, except that A takes A's child to B for treatment of the child's severe peanut allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access. A group health plan or health insurance issuer offering group or individual health insurance coverage described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a

participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care and is not limited to a physician.

(B) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) Application of paragraph. A group health plan or health insurance issuer offering group or individual health insurance coverage is described in this paragraph if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) Construction. Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) Examples. The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(ii) Conclusion. In this Example 1, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) Facts. Same facts as Example 1 except that A seeks gynecological services from C, an out-of-network provider.

(ii) Conclusion. In this Example 2, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) Facts. Same facts as Example 1 except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(ii) Conclusion. In this Example 3, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for a scheduled cesarean section.

(ii) Conclusion. In this Example 4, the plan requirement for prior authorization before providing benefits for a scheduled cesarean section does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to services for treatments, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) Notice of right to designate a primary care provider. (i) In general. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights –

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, that any participating physician who specializes in pediatrics as the child's primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) Timing. In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) Model language. The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

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Because [name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider, you have the right to designate any primary care provider who participates in the network of [name of plan or coverage] and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the plan administrator at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, insert:

If you have a child who is enrolled in [name of group health plan or health insurance issuer], you have the right to designate any pediatrician who participates in the network of [plan or coverage] and who is available to accept your child as your child's primary care provider. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one.] For information on how to select a pediatrician, and for a list of the participating pediatricians, contact the plan administrator at [insert contact information].

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary or enrollee of a primary care provider, insert:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain obstetrical or gynecological care from a health care professional who specializes in obstetrics or gynecology and who participates in the network of [name of group health plan or issuer]. Such a health care professional, however, may be required to comply with certain procedures required by [name of group health plan or issuer] including obtaining prior authorization for certain services, following a pre-approved treatment plan, or for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the plan administrator at [insert contact information].

(b) Coverage of emergency services.—(1) Scope. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) General rules. A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner –

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than –

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code; or

(C) Applicable cost sharing.

(3) Cost-sharing requirements – (i) Copayments and coinsurance. Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this

paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is [the median of these amounts irrespective of the number of providers charging][the median of these amounts, ranking them by the number of providers with which the rates were negotiated], excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) Other cost sharing. Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) Examples. The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to services in an emergency department of a hospital.

Example 1. (i) Facts. A group health plan imposes a 25 percent coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual provides notice to the plan within two business days after the day an individual receives screening or treatment in an emergency department, the plan reduces the coinsurance rate to 15 percent.

(ii) Conclusion. In this Example 1, the requirement to provide notice in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required notice before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a \$60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) Conclusion. In this Example 2, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it receive notification rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) Facts. A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service.

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Each provider has agreed to provide the service for a certain amount. Among all the providers there are five amounts: \$85, \$100, \$110, \$120, and \$150. Under the agreement, the plan agrees to pay the providers 80 percent of the agreed amount, with the individual receiving the service responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 3, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$110 (\$88).

Example 4. (i) Facts. Same facts as Example 3. Subsequently, the plan adds a provider to its network and agrees to pay the provider 80 percent of \$170 for the emergency service, with the individual responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 4, the median amount among those agreed to for the emergency service is \$115. (Because there is no one middle amount among \$85, \$100, \$110, \$120, \$150, and \$170, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$115 (\$92).

Example 5. (i) Facts. Same facts as Example 4. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50 percent of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is \$116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, would be \$80.

(ii) Conclusion. In this Example 5, the plan is responsible for paying \$92.80, 80 percent of \$116. The median amount among those agreed to for the emergency service is \$115 and the amount the plan would pay is \$92 (80 percent of \$115); the amount calculated using the same method the plan uses to determine payments for out-of-network services -- \$116 -- excluding the in-network 20 percent coinsurance, is \$92.80; and the Medicare payment is \$80. Thus, the greatest amount is \$92.80. The individual is responsible for the remaining \$32.20 charged by the out-of-network provider.

Example 6. (i) Facts. Same facts as Example 5. The group health plan generally imposes a \$250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of network.

(ii) Conclusion. In this Example 6, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered

individual has not satisfied the higher deductible that applies generally to all health care provided out of network.

(4) Definitions. The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions, and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) Emergency services. The term emergency services means, with respect to an emergency medical condition –

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) Stabilize. The term to stabilize, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to all grandfathered health plans).

2. Section 147.120 is amended by revising paragraph (d) to read as follows:

(d) Uniformity irrespective of age.—(1) In general. Subject to paragraph (d)(2) of this section, the terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(2) Preexisting condition exclusions for children age 19 and older before 2014. For plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or health insurance coverage may impose a preexisting condition exclusion (in the group market, consistent with the rules of section 146.111 of this Part) on children who are age 19 or older even though this is prohibited with respect to children under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

From: [Mayhew, James A. \(CMS/CPC\)](#)
To: [Larsen, Steven \(HHS/OCIIO\)](#); [Angoff, Jay \(HHS/OCIIO\)](#); [Pollitz, Karen \(HHS/OCIIO\)](#)
Cc: [Schulkin, Vicki \(HHS/OGC\)](#); [Shaw, Adam \(CMS/CM\)](#)
Subject: FW: Clean Drafts
Date: Friday, June 11, 2010 6:24:00 PM
Attachments: [Pkg of 6 Reg Text 6.11.10 6pm clean.doc](#)
[Pkg of 6 Joint Preamble 6.11.10 6pm clean.doc](#)

Here is the latest draft of the "six pack" package (lifetime and annual limits, pre-existing condition exclusions, rescissions, discrimination in favor of highly compensated individuals, patient protections, and opt-outs of non-Federal governmental plans).

This is scheduled to go to OMB by COB Monday, so please submit your comments to me by 10:00 am Monday.

Thanks!

>-----Original Message-----

>From: Baum, Beth - EBSA [<mailto:baum.beth@dol.gov>]

>Sent: Friday, June 11, 2010 6:20 PM

>To: Corrigan, Dara (HHS/ASPE); Mayhew, James A. (CMS/CPC); Kosin, Donald
>(HHS/OGC); Dailey, Joan (HHS/OGC); Stafford, Leslie (HHS/OGC);

>Weinheimer Russell E; Knopf Kevin - OTP; Russ Weinheimer - HOME; Kevin

>Knopf - HOME; Levin Karen; Schumacher, Elizabeth - EBSA; Baum, Beth -

>EBSA; Turner, Amy - EBSA

>Subject: Clean Drafts

>

>This is what we are going to circulate internally for comment over the
>weekend.

>

>The plan is to meet at 11am to start incorporating comments and send to

>OMB by COB Monday.

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** This document currently represents a single “joint” DOL/IRS/HHS reg text. The final document will actually include 3 parallel regulations – one IRS regulation (26 CFR Part 54), followed by one DOL regulation (29 CFR Part 2590), followed by one HHS regulation (45 CFR Parts 144, 146, and 147). The IRS and HHS reg texts will be re-formatted to include the correct citations for their Part. In addition, DOL and IRS will delete references to requirements for issuers of individual market coverage, but will include cross-references as appropriate.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 continues to read as follows:

Authority:

29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor’s Order 6-2009, 74 FR 21524 (May 7, 2009).

Subpart B—Other Requirements

2. Section 2590.701-2 is amended by revising the definition of preexisting condition exclusion to read as follows:

§ 2590.701-2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or

individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

3. Section 2590.701-3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 2590.701-2 of this Part.

* * * * *

4. Section 2590.715-2704 is added to Subpart C to read as follows:

§ 2590.715-2704 Prohibition of preexisting condition exclusions.

(a) No preexisting condition exclusions—(1) In general. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701-2 of this Part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must

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comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704).

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13-year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13-year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the child is under 19 years of age and the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13-year-old child.

5. Section 2590.715-2711 is added to Subpart C to read as follows:

§2590.715-2711 No lifetime or annual limits.

(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual

health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage,

may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) Authority of the Secretary to grant waivers. For plan years (in the individual market, policy years) beginning before January 1, 2014, the Secretary [of Health and Human Services] may establish a program under which the requirements of this section relating to annual limits may be waived for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under this section if compliance with this section will result in a significant decrease in access to benefits under the plan or health insurance coverage or a significant increase in premiums for the plan or health insurance coverage.

(e) Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit.

(1) In general. The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits ended under a group health plan or group or individual health insurance coverage by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a limit on the dollar value of all benefits under the group health plan or group or individual health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) Notice and enrollment opportunity requirements – (i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan – or group or individual health insurance coverage – described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The notice may be provided to an employee on behalf of the employee's dependent (in the individual market, to the primary subscriber on behalf of the primary subscriber's dependent). In addition, for a group health plan or group health insurance coverage, the notice

may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an employee whose dependent is entitled to an enrollment opportunity under this paragraph (e), the obligation to provide the notice of enrollment opportunity under this paragraph (e)(2) with respect to that dependent is satisfied for both the plan and the issuer.

(3) Effective date of coverage. In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §2590.701-6(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) Examples. The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan has a lifetime limit on the dollar value of all benefits. Individual B, an employee of Y, was enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, B incurred a claim

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for benefits that exceeded the lifetime limit under Y's plan and ceased to be enrolled in the plan. On or before January 1, 2011, Y's group health plan gives B written notice of B's right to enroll in the plan, and that B can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this paragraph (e) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual D, an employee of Z, and Individual E, D's child, were enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E incurred a claim for benefits that exceeded the lifetime limit under Z's plan. D dropped family coverage but remains an employee of Z.

(ii) Conclusion. In this Example 2, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) Facts. Same facts as Example 2, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the prohibition on lifetime limits applies to all grandfathered health plans, while the prohibition on annual limits, including the special rules regarding restricted annual limits, applies to group health plans and group health insurance coverage that are grandfathered health plans, but do not apply to individual health insurance coverage that is a grandfathered health plan).

6. Section 2590.715-2712 is added to Subpart C to read as follows:

§ 2590.715-2712 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide [at least 30 days] advance notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if –

(i) The cancellation or discontinuance of coverage has only a prospective effect; or

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

(3) The rules of this paragraph (a) are illustrated by the following examples:

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Example 1. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A visited a psychologist on two occasions, six years ago. A is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's visits to the psychologist, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example 1, the plan cannot rescind A's coverage because A's failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) Facts. An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual B has coverage under the plan as a full-time employee. The employer reassigns B to a part-time position. Under the terms of the plan, B is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from B, and paying claims submitted by B. After a routine audit, the plan discovers that B no longer works at least 30 hours a week. The plan rescinds B's coverage effective as of the date that B changed from a full-time employee to a part-time employee.

(ii) Conclusion. In this Example 2, the plan cannot rescind B's coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for B prospectively, subject to other applicable Federal and State laws.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

7. Section 2590.715-2714 is amended by revising paragraphs (d) and (h) to read as follows:

(d) Uniformity irrespective of age.—(1) In general. Subject to paragraph (d)(2) of this section, the terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(2) Preexisting condition exclusions for children age 19 and older before 2014. For plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or health insurance coverage may impose a preexisting condition exclusion (consistent with the rules of section 2590.701-3 of this Part [HHS add: “in the group market”]) on children who are age 19 or older even though this is prohibited with respect to children under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

8. Section 2590.715-2716 is added to Subpart C to read as follows:

§ 2590.715-2716 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code (prohibiting discrimination in favor of highly compensated individuals under a self-insured medical expense reimbursement plan as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-insured plan) under this section as if the group health plan were a self-insured medical expense reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the rules prohibiting discrimination in favor of highly compensated individuals by insured group health plans do not apply to grandfathered health plans).

9. Section 2590.715-2719A is added to Subpart C to read as follows:

§ 2590.715-2719A Patient protections.

(a) Choice of health care professional – (1) Designation of primary care provider—(i) In general. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) Example. The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) Facts. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any participating primary care provider who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan

designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) Conclusion. In this Example, the plan has satisfied the requirements of paragraph (a) of this section.

(2) Designation of pediatrician as primary care provider—(i) In general. If a group health plan or health insurance issuer offering group or individual health insurance coverage requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) Construction. Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) Examples. The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An HMO designates for each enrollee a physician who specializes in internal medicine to serve as the primary care provider for the enrollee and the enrollee's family. Enrollee A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

(ii) Conclusion. In this Example 1, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) Facts. Same facts as Example 1, except that A takes A's child to B for treatment of the child's severe peanut allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access. A group health plan or health insurance issuer offering group or individual health insurance coverage described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care and is not limited to a physician.

(B) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services,

pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) Application of paragraph. A group health plan or health insurance issuer offering group or individual health insurance coverage is described in this paragraph if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) Construction. Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) Examples. The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(ii) Conclusion. In this Example 1, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) Facts. Same facts as Example 1 except that A seeks gynecological services from C, an out-of-network provider.

(ii) Conclusion. In this Example 2, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) Facts. Same facts as Example 1 except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(ii) Conclusion. In this Example 3, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for a scheduled cesarean section.

(ii) Conclusion. In this Example 4, the plan requirement for prior authorization before providing benefits for a scheduled cesarean section does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to services for treatments, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) Notice of right to designate a primary care provider. (i) In general. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights –

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, that any participating physician who specializes in pediatrics as the child's primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) Timing. In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) Model language. The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

Because [name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider, you have the right to designate any primary care provider who participates in the network of [name of plan or coverage] and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the plan administrator at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, insert:

If you have a child who is enrolled in [name of group health plan or health insurance issuer], you have the right to designate any pediatrician who participates in the network of [plan or coverage] and who is available to accept your child as your child's primary care provider. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one.] For information on how to select a

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pediatrician, and for a list of the participating pediatricians, contact the plan administrator at [insert contact information].

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary or enrollee of a primary care provider, insert:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain obstetrical or gynecological care from a health care professional who specializes in obstetrics or gynecology and who participates in the network of [name of group health plan or issuer]. Such a health care professional, however, may be required to comply with certain procedures required by [name of group health plan or issuer] including obtaining prior authorization for certain services, following a pre-approved treatment plan, or for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the plan administrator at [insert contact information].

(b) Coverage of emergency services.—(1) Scope. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) General rules. A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner –

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than –

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code; or

(C) Applicable cost sharing.

(3) Cost-sharing requirements – (i) Copayments and coinsurance. Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is

[the median of these amounts irrespective of the number of providers charging][the median of these amounts, ranking them by the number of providers with which the rates were negotiated], excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) Other cost sharing. Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) Examples. The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to services in an emergency department of a hospital.

Example 1. (i) Facts. A group health plan imposes a 25 percent coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of

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network. If a covered individual provides notice to the plan within two business days after the day an individual receives screening or treatment in an emergency department, the plan reduces the coinsurance rate to 15 percent.

(ii) Conclusion. In this Example 1, the requirement to provide notice in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required notice before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a \$60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) Conclusion. In this Example 2, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it receive notification rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) Facts. A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers there are five amounts: \$85, \$100, \$110, \$120, and \$150. Under the agreement, the plan agrees to pay the providers 80 percent of the agreed amount, with the individual receiving the service responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 3, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$110 (\$88).

Example 4. (i) Facts. Same facts as Example 3. Subsequently, the plan adds a provider to its network and agrees to pay the provider 80 percent of \$170 for the emergency service, with the individual responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 4, the median amount among those agreed to for the emergency service is \$115. (Because there is no one middle amount among \$85, \$100, \$110, \$120, \$150, and \$170, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$115 (\$92).

Example 5. (i) Facts. Same facts as Example 4. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the

service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50 percent of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is \$116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, would be \$80.

(ii) Conclusion. In this Example 5, the plan is responsible for paying \$92.80, 80 percent of \$116. The median amount among those agreed to for the emergency service is \$115 and the amount the plan would pay is \$92 (80 percent of \$115); the amount calculated using the same method the plan uses to determine payments for out-of-network services -- \$116 -- excluding the in-network 20 percent coinsurance, is \$92.80; and the Medicare payment is \$80. Thus, the greatest amount is \$92.80. The individual is responsible for the remaining \$32.20 charged by the out-of-network provider.

Example 6. (i) Facts. Same facts as Example 5. The group health plan generally imposes a \$250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of network.

(ii) Conclusion. In this Example 6, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network.

(4) Definitions. The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her

unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions, and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) Emergency services. The term emergency services means, with respect to an emergency medical condition –

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) Stabilize. The term to stabilize, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to all grandfathered health plans).

10. Section 146.180 is amended as follows:

- A. Revising paragraph (a)(1).
- B. Adding a new paragraph (a)(2).
- C. Renumbering paragraphs (a)(2), (a)(3) and (a)(4) as (a)(3), (a)(4) and (a)(5), respectively.

- D. Replacing “2706” with “2727” each place it appears in paragraph (a)(1)(i)(F) and in Example 1 of paragraph (a)(3) (previously designated as (a)(2)).
- E. Making a conforming change to paragraph (a)(4)(i) (previously designated as (a)(3)(i)).
- F. Updating paragraph (c) to reflect the current address to which exemption elections may be mailed and providing a facsimile number to which elections may be faxed as an alternative to mailing elections.
- G. Removing the outdated parenthetical reference to § 146.125(a)(2) in paragraph (f)(2)(ii).
- H. Making a conforming change to paragraph (f)(3)(i).
- I. Adding a conforming sentence at the end of Example 1 in paragraph (h)(4)(i).
- J. Updating Example 4 in paragraph (i)(2)(iv).

The revisions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) Requirements subject to exemption—(1) Non-collectively bargained plans. (i) Plan years commencing before September 23, 2010. A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), for plan years commencing before September 23, 2010, from any or all of the following requirements:

- (A) Limitations on preexisting condition exclusion periods described in § 146.111.
- (B) Special enrollment periods for individuals and dependents described in § 146.117.
- (C) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements in § 146.121(a)(1)(vi) and § 146.122 that prohibit discrimination with respect to genetic information.
- (D) Standards relating to benefits for mothers and newborns described in § 146.130.

(E) Parity in the application of certain limits to mental health and substance use disorder benefits described in § 146.136.

(F) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2727 of the PHS Act.

(G) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(ii) Plan years beginning on or after September 23, 2010. A sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan for plan years beginning on or after September 23, 2010, only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) or (G). With respect to those plan years, the notices required by paragraph (f) of this section must reflect the limitations set forth in this paragraph (a)(1)(ii).

(iii) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1)(i). The plan year commences September 1 each year. The plan is not subject to the limitations of paragraph (a)(1)(ii) until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(iv) Example 2. Same facts as in Example 1, except the plan year commences October 1 each year. The plan is subject to the limitations of paragraph (a)(1)(ii) beginning with the plan year that commences on October 1, 2010. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(2) Collectively bargained plans. (i) Special rule. Without regard to paragraph (b)(2) of this section, a group health plan that is governed by a collective bargaining agreement that was ratified before March 23, 2010, is subject to the limitations set forth in paragraph (a)(1)(ii) beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement. The notices required by paragraph (f) of this section, with respect to the first plan year subject to the limitations of paragraph (a)(1)(ii), must reflect those limitations.

(ii) Example. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1)(i) of this section. The collective bargaining agreement applies to five plan years, October 1, 2007 through September 30, 2012. For the plan year that commences on October 1, 2012, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1)(i)(A), (B) and (C). Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(3) Limitations. * * *

(A) Example 1. A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

* * *

(4) Stop-loss or excess risk coverage. For purposes of this section—(i) Subject to paragraph (a)(4)(ii), * * *

(5) Construction. * * *

* * * * *

(c) Mailing address. The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Medicare Enrollment and Appeals Group, CM, ATTN: HIPAA Opt-Out, 7500 Security Boulevard, C2-12-16, Baltimore, MD 21244-1850. Alternatively, the plan sponsor may fax the exemption election to 410-786-8001.

* * * * *

(f) * * *

(2) * * *

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, * * *

(3) * * *

(i) The specific requirements described in paragraphs (a)(1) or (a)(2) of this section, as applicable, from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

* * * * *

(h) * * *

(4) * * *

(i) Example 1. (A) * * *

(B) * * * However, regarding plan years that begin on or after September 23, 2010, the plan sponsor no longer can elect to exempt its plan from prohibitions against enrollment discrimination based on health status-related factors.

* * *

(i) * * *

(2) * * *

(iv) Example 4: A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from the requirements of paragraph (a)(1)(i)(E) of this section. The collective bargaining agreement applies to five plan years, 2007 through 2011. For the

first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2007 through December 31, 2011. Prior to the dissemination of the annual notice for the 2010 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2007 through December 31, 2011. Accordingly, CMS would not invalidate the election for the 2010 plan year.

* * * * *

[Billing Codes: 4830-01-P; 4510-29-P; 4120-01-P]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 54 and 602

TD

RIN 1545-BJ61

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB43

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

OCHIO-XXXX-IFC

45 CFR Parts 144, 146, and 147

RIN XXXX-XXXX

**Interim Final Rules under the Patient Protection and Affordable Care Act Regarding
Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Prohibition on
Discrimination in Favor of the Highly Compensated, Patient Protections, and Non-Federal
Governmental Plans**

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits
Security Administration, Department of Labor; Office of Consumer Information and Insurance
Oversight, Department of Health and Human Services.

PRELIMINARY DISCUSSION DRAFT of 6.11.10

Not for Public Distribution

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, prohibition on discrimination in favor of highly compensated individuals, patient protections, and non-federal governmental plans.

DATES: Effective date. These interim final regulations are effective on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Comment date. Comments are due on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Applicability date. These interim final regulations generally apply to group health plans and group health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**. These interim final regulations generally apply to individual health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines.

No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB43, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Email: [E-OHPSCA\[XXXX\].EBSA@dol.gov](mailto:E-OHPSCA[XXXX].EBSA@dol.gov).

- Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: RIN 1210-AB43.

Comments received by the Department of Labor will be posted without change to www.regulations.gov and www.dol.gov/ebsa, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCHIO-9991-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.
2. By regular mail. You may mail written comments to the following address ONLY:
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services,

Attention: OCIO-9991-IFC,

P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services,

Attention: OCIO-9991-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to

leave their comments in the OCIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the

PRELIMINARY DISCUSSION DRAFT of 6.11.10

Not for Public Distribution

headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-120399-10, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: CC:PA:LPD:PR (REG-120399-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-120399-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786-1565.

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's website (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for

consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp) and information on health reform can be found at <http://www.healthreform.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of part A of title XXVII of the PHS Act applicable under ERISA and the Code to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if those provisions of the PHS Act were included in ERISA and the Code. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The

¹ The term “group health plan” is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term “health plan”, as used in other provisions of title I of the Affordable Care Act. The term “health plan” does not include self-insured group health plans.

preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of the Affordable Care Act are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers stricter requirements than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations implementing the revised PHS Act sections 2701 through 2719A in several phases. The first publication in this series was a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). The second publication was interim final regulations implementing PHS Act section 2714 (requiring dependent coverage of children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third publication was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on June 17, 2010 (75 FR XXXXX). These interim final regulations are being published to implement PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), 2716 (prohibiting discrimination in favor of highly compensated individuals), 2719A (regarding patient protections), and 2722 (regarding the application of the Affordable Care Act provisions to non-

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

Federal governmental plans). PHS Act section 2704 generally is effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014. However, with respect to enrollees, including applicants for enrollment, who are under 19 years of age, PHS Act section 2704 is effective for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.³ The rest of these provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

II. Overview of the Regulations

A. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815-2704T, 29 CFR 2590.715-2704, 45 CFR 147.108)

Section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA⁴ rules relating to preexisting condition exclusions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under certain circumstances. The Affordable Care Act provision prohibits any preexisting condition exclusions imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1,

³ Section 1255 of the Affordable Care Act. See also section 10103(e)-(f) of the Affordable Care Act.

⁴ HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

HIPAA generally defines a preexisting condition exclusion⁵ as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

The protections in the new PHS Act section 2704 generally apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014. The Affordable Care Act provides, however, that these protections apply with respect to enrollees under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. An enrollee under age 19 thus could not be denied benefits based on a preexisting condition. In order for an individual to receive the same protection that applies in the case of such an enrollee, the individual similarly could not be denied benefits (through denial of enrollment or denial of specific benefits) based on a preexisting condition. Thus, for plan years (in the individual market, for policy years) beginning on or after September 23, 2010, PHS Act section 2704 protects individuals under age 19 with a preexisting condition from being denied coverage under a plan or health insurance coverage (through denial of enrollment or denial of specific benefits) based on the preexisting condition.

⁵ Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1); after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1). See also ERISA section 701(b)(1) and Code section 9801(b)(1).

These interim final regulations do not change the HIPAA rule that a plan's or issuer's exclusion of benefits for a condition from the plan or policy regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. This point is still relevant for these interim final regulations and is illustrated with examples in the HIPAA regulations on preexisting condition exclusions.⁶ (Other requirements of Federal or State law, however, may prohibit certain benefit exclusions.)

The interim final regulations under PHS Act section 2714 (relating to the continuation of dependent coverage until a child turns age 26) (75 FR 27122, May 13, 2010) provide that the terms of a plan or policy for dependent coverage cannot vary based on the age of a child, except for children age 26 or older. These interim final regulations amend those regulations to clarify that, for plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or policy may impose a preexisting condition exclusion (consistent with the rules of 26 CFR 54.9801-3, 29 CFR 2590.701-3, and 45 CFR 146.111) on children who are age 19 or older even though this is prohibited with respect to children under age 19.

Application to grandfathered health plans. Under the statute and these interim final regulations, a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704. See 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 regarding status as a grandfathered health plan.

B. PHS Act Section 2711, Lifetime and Annual Limits (26 CFR 54.9815-2711T, 29 CFR 2590.715-2711, 45 CFR 147.126)

⁶ See Examples 6, 7, and 8 in 26 CFR 54.9801-3(a)(1)(ii), 29 CFR 701-3(a)(1)(ii), 45 CFR 146.111(a)(1)(ii).

Section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits. However, these interim final regulations provide that the annual limit rules do not apply to health flexible spending arrangements.⁷

The statute also allows “restricted annual limits” with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. In addition, the statute provides that, with respect to benefits that are not essential health benefits, a plan or issuer may impose annual or lifetime per-individual limits on specific covered benefits. Rather than provide a definition of “essential health benefits,” these interim final regulations cross-reference section 1302(b) of the Affordable Care Act and applicable regulations.⁸

These interim final regulations clarify that the prohibition under PHS Act section 2711 does not prevent a plan or issuer from excluding all benefits for a condition, but if any benefits are provided for a condition, then the requirements of the rule apply. Therefore, an exclusion of all benefits for a condition is not considered to be an annual or lifetime dollar limit.

The statute and these interim final regulations provide that for plan years (in the individual market, policy years) beginning before January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may establish a restricted annual limit on the dollar value of essential health benefits. The statute provides that in defining the term restricted annual limit, the Departments ensure that access to needed services is made available with a minimal impact on premiums.

⁷ Section 9005 of the Affordable Care Act specifically limits the annual amount of salary reduction contributions for health flexible spending arrangements.

⁸ Regulations under section 1302(b) of the Affordable Care Act have not yet been issued.

In establishing the restricted annual limit, the Departments considered several factors: (1) the current use of annual limits in the group and individual market; (2) the average premium impact of imposing different annual limits on the individual, small group, and large group markets; (3) the number of individuals who will continue to have annual medical expenses that exceed an annual limit; and (4) the possibility that a plan or issuer would switch to an annual limit when lifetime limits are prohibited.

In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, these interim final regulations adopt a three-year phased approach for restricted annual limits. Under these interim final regulations, annual limits on the dollar value of benefits that are essential health benefits may not be less than the following amounts for plan years (in the individual market, policy years) beginning before January 1, 2014:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, \$750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, \$1.25 million; and
- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2 million.

As these are minimums for plan years (in the individual market, policy years) beginning before 2014, plans or issuers may always use higher annual limits or impose no limits. Plans and policies with plan or policy years that begin between September 23 and December 31 have more than one plan or policy year under which the \$2 million minimum annual limit is available;

however, a plan or policy generally may not impose an annual limit for a plan year beginning after December 31, 2013.

The minimum annual limits for plan or policy years beginning before 2014 apply on an individual-by-individual basis. Thus, any overall annual dollar limit on benefits applied to families may not operate to deny a covered individual the minimum annual benefits for the plan year (in the individual market, policy year). These interim final regulations clarify that, in applying annual limits for plan years (in the individual market, policy years) beginning before January 1, 2014, the plan or health insurance coverage may only take into account essential health benefits.

Although the restricted annual limits provided in these interim final regulations are designed to ensure, in the vast majority of cases, that individuals would have access to needed services with a minimal impact on premiums, the Departments recognize that for a small minority of plans or health insurance coverage, compliance with the annual limit requirement prescribed in these interim final regulations could have the effect of either denying access to needed services or having more than a minimal impact on premiums. In order to avoid having individuals with such coverage be denied access to needed services or experience more than a minimal impact on premiums, these interim final regulations provide for the Secretary [of Health Human Services] to establish a program under which the requirements relating to annual limits may be waived if compliance with these interim final regulations will result in a significant decrease in access to benefits or a significant increase in premiums. The Departments request comments on the scope of the program. For example, should both insured and self-insured coverage be eligible for the program? Should certain low-cost benefit plans (sometimes referred to as mini-med plans) or health reimbursement arrangements be eligible? Should the waiver

apply to the entire period before January 1, 2014 or be granted on a plan-year-by-plan-year basis?

These interim final regulations require that individuals who reached a lifetime limit under a plan or health insurance coverage and are otherwise still eligible under the plan or health insurance coverage are provided with a notice that the lifetime limit no longer applies. If such an individual is no longer enrolled in the plan or health insurance coverage, these interim final regulations also provide an enrollment (in the individual market, reinstatement) opportunity for such individuals. In the individual market, this reinstatement opportunity does not apply to individuals who reached their lifetime limits in individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in a family policy in the individual market while other family members remain in the coverage. These notices and the enrollment opportunity must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

Application to grandfathered health plans. The statute and these interim final regulations relating to the prohibition on lifetime limits apply to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the prohibition on annual limits, including the special rules regarding restricted annual limits for plan years beginning before January 1, 2014, apply to group health plans and group health insurance

coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage.⁹

C. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815-2712T, 29 CFR 2590.715-2712, 45 CFR 147.128)

PHS Act section 2712 provides rules regarding rescissions of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard applies to all rescissions, whether in the group or individual insurance market, or self-insured coverage. These rules also apply regardless of any contestability period of the plan or issuer.

These interim final regulations include several clarifications regarding the standards for rescission. First, these interim final regulations clarify that the rules of PHS Act section 2712 apply whether the rescission applies to a single individual or an entire group of individuals. Thus, for example, if an issuer attempted to rescind coverage of an entire employer group based on the actions of an individual within the group, the standards of these interim final regulations would apply. Second, these interim final regulations clarify that the rules of PHS Act section 2712 apply to representations made by the individual or a person seeking coverage on behalf of

⁹ Note also that the regulations issued under section 1251 of the Affordable Care Act include a rule relating to retention of status as a grandfathered health plan based on changes to annual limits. Under those regulations, three different situations are addressed. First, a plan or health insurance coverage that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits. Second, a plan or health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010. Third, a plan or health insurance coverage that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

the individual. Thus, if a plan sponsor seeks coverage from an issuer for an entire employment-based group and makes representations, for example, regarding the prior claims experience of the group, the standards of these interim final regulations would also apply. Finally, PHS Act section 2712 refers to acts or practices that constitute fraud. These interim final regulations clarify that, to the extent that an omission constitutes fraud, that omission would permit the plan or issuer to rescind coverage under this section. An example in these interim final regulations illustrates the application of the rule to misstatements of fact that are inadvertent.

For purposes of these interim final regulations, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission, and neither is a cancellation or discontinuance of coverage that is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

PHS Act section 2712 adds a new advance notice requirement when coverage is rescinded where still permissible. Specifically, the second sentence in section 2712 provides that coverage may not be cancelled unless prior notice is provided, and then only as permitted under PHS Act sections 2702(c) and 2742(b). Under these interim final regulations, even if prior notice is provided, rescission is only permitted in cases of fraud or an intentional

misrepresentation of a material fact as permitted under the cited provisions.¹⁰ While this reference appears redundant, it is consistent with the first sentence.

These interim final regulations provide that a group health plan, or a health insurance issuer offering group health insurance coverage, must provide [at least 30 days] advance notice to an individual before coverage may be rescinded.¹¹ The notice must be provided regardless of whether the rescission is of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group.

These interim final regulations also clarify that other requirements of Federal or State law may apply in connection with a rescission of coverage.

Application to grandfathered health plans. The rules regarding rescissions and advance notice apply to all grandfathered health plans.

D. PHS Act Section 2716, Prohibiting Discrimination in Favor of Highly Compensated Individuals (26 CFR 54.9815-2716T, 29 CFR 2590.715-2716, 45 CFR 147.132)

PHS Act section 2716 and these interim final regulations incorporate the nondiscrimination rules of section 105(h) of the Code and apply them to group health plans that are not self-insured plans. Section 105(h) generally prohibits self-insured medical reimbursement plans from discriminating in favor of highly compensated individuals in eligibility classifications or in benefits. Section 105(b) of the Code generally excludes from an employee's income (otherwise subject to federal income taxation) amounts received as

¹⁰ The reference to section 2702(c) appears to be incorrect. After the amendments made by the Affordable Care Act, PHS Act section 2702(c) addresses network requirements for guaranteed availability of coverage. It seems more likely that the intended cross-reference is to new PHS Act section 2703(b), relating to nonrenewal of coverage in the group market, which corresponds to the other cross-reference, in PHS Act section 2742(b), to nonrenewal of coverage in the individual market. Both these provisions contain the fraud and intentional misrepresentation of material fact standard included in the first sentence of section 2712. In order to avoid confusion, these interim final regulations apply the fraud and misrepresentation standard found in sections 2703(b) and 2742(b).

¹¹ Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

reimbursement of medical care expenses for the employee or the employee's spouse, dependents, or children who have not attained age 27 by the end of the taxable year. If a self-insured medical reimbursement plan does not comply with the requirements of section 105(h), the general exclusion from income (and hence, from federal income taxation) under section 105(b) does not apply with respect to highly compensated individuals. Highly compensated individuals are defined in section 105(h).

PHS Act section 2716 and these interim final regulations incorporate the substantive nondiscrimination requirements of Code section 105(h) but not the tax sanctions. An insured group health plan failing to comply with the nondiscrimination requirements of Code section 105(h) is subject to the sanctions and remedies that generally apply for a plan failing to comply with the requirements of chapter 100 of the Code (generally, an excise tax of \$100 per day per individual discriminated against for each day the plan does not comply with the requirement), part 7 of ERISA (a civil action to enjoin a noncompliant act or practice or for appropriate equitable relief), or title XXVII of the PHS Act (civil money penalties of \$100 per day per individual discriminated against for each day the plan does not comply with the requirement). Thus, if a self-insured plan fails to comply with Code section 105(h), highly compensated individuals lose a tax benefit; if an insured group health plan fails to comply with Code section 105(h), the plan is subject to a civil action to compel it to provide nondiscriminatory benefits and the plan or plan sponsor is subject to an excise tax or civil money penalty of \$100 per day per individual discriminated against. Rather than restate the rules under section 105(h) of the Code, these interim final regulations incorporate by reference those rules and applicable regulations.

Questions have arisen as to how this rule applies to health insurance policies purchased by employers for employees on an individual-by-individual basis. That is, do these rules apply if

an employer buys an individual policy for a highly compensated employee, separate from the health coverage offered to other employees? The Departments proposed rules on December 30, 2004 (69 FR 78800) that provide, among other things, that if a principal purpose of establishing separate plans is to evade any requirement of law, then the separate plans will be considered a single plan to the extent necessary to prevent the evasion. The Departments expect to finalize these rules soon.

The regulations under section 105(h) of the Code, prohibiting discrimination in favor of highly compensated individuals under self-insured medical expense reimbursement plans, were issued in _____. The Department of the Treasury and the IRS request comments on what additional guidance relating to the application of section 105(h) would be helpful, especially as applied to insured group health plans.

Application to grandfathered health plans. The rules prohibiting discrimination in favor of highly compensated individuals by insured group health plans do not apply to grandfathered health plans (but the rules of Code section 105(h) continue to apply to self-insured plans).

D. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815-2719AT, 29 CFR 2590.715-2719A, 45 CFR 147.138)

Section 2719A of the PHS Act imposes, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of a health care professional and requirements relating to benefits for emergency services. The three requirements relating to the choice of health care professional apply only with respect to a plan or health insurance coverage with a network of providers.¹² Thus, a plan or issuer that has not negotiated with any provider for the delivery of health care but merely reimburses individuals

¹² The statute and these interim final regulations refer to providers both in terms of their participation and in terms of a network. In both situations, the intent is to refer to a provider that has a contractual relationship or other arrangement with a plan or issuer.

covered under the plan for their receipt of health care is not subject to the requirements relating to the choice of a health care professional. However, such plans or health insurance coverage are subject to requirements relating to benefits for emergency services. These interim final regulations reorder the statutory requirements so that all three of the requirements relating to the choice of a health care professional are together and add a notice requirement for those three requirements.

1. Choice of Health Care Professional

The statute and these interim final regulations provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In accordance with paragraph (a)(4) of these interim final regulations, the plan or issuer must provide a notice informing each participant (or in the individual market, the primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

The statute and these interim final regulations impose a requirement for the designation of a pediatrician similar to the requirement for the designation of a primary care physician. Specifically, if a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the notice requirements of paragraph (a)(4) of

these interim final regulations. The general terms of the plan or health insurance coverage regarding pediatric care otherwise are unaffected, including any exclusions with respect to coverage of pediatric care.

The statute and these interim final regulations also provide rules for a group health plan, or a health insurance issuer offering group or individual health insurance coverage, that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. In such a case, the plan or issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology. The plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. Nothing in these interim final regulations precludes the plan or issuer from requiring an in-network obstetrical or gynecological provider to otherwise adhere to policies and procedures regarding referrals, prior authorization for treatments, and the provision of services pursuant to a treatment plan approved by the plan or issuer. The plan or issuer must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the professional who specializes in obstetrics or gynecology as the authorization of the primary care provider. For this purpose, a health care professional who specializes in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care, and is not limited to a physician.

The general terms of the plan or coverage regarding exclusions of coverage with respect to obstetrical or gynecological care are otherwise unaffected. These interim final regulations do not preclude the plan or issuer from requiring that the obstetrical or gynecological provider notify the primary care provider or the plan or issuer of treatment decisions.

When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization. Accordingly, these interim final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. Model language is provided in these interim final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

2. Emergency Services

If a plan or health insurance coverage provides any benefits with respect to emergency services in an emergency department of a hospital, the plan or issuer must cover emergency services in a way that is consistent with these interim final regulations. These interim final regulations require that a plan providing emergency services must do so without any prior authorization (even if the emergency services are provided out of network) and without regard to whether the health care provider furnishing the emergency services is an in-network provider with respect to the services. The emergency services must be provided without regard to any other term or condition of the plan or health insurance coverage other than the exclusion or

coordination of benefits, an affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code, or applicable cost-sharing requirements. For a plan or health insurance coverage with a network of providers that provides benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or limitations that apply to in-network emergency services.

Additionally, for a plan or health insurance coverage with a network, these interim final regulations provide rules for cost-sharing requirements for emergency services that are expressed as a copayment amount or coinsurance rate, and other cost-sharing requirements. Cost-sharing requirements expressed as a copayment amount or coinsurance rate imposed for out-of-network emergency services cannot exceed the cost-sharing requirements that would be imposed if the services were provided in-network. A plan or issuer satisfies this requirement if it provides benefits for out-of-network emergency services in an amount equal to the greatest of three possible amounts—

- (1) The amount negotiated with in-network providers for the emergency service furnished;
- (2) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges); or
- (3) The amount that would be paid under Medicare for the emergency service.¹³

Each of these three amounts is calculated excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

¹³ As of the date of publication of these interim final regulations, these rates are available to the public at <http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf>.

In connection with determining the first amount above, for plans and health insurance coverage under which there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the amount is disregarded, meaning that the greatest amount is going to be either the out-of-network amount or the Medicare amount.

Additionally, with respect to determining the first amount, if a plan or issuer has more than one negotiated amount with in-network providers for a particular emergency service, the amount is [the median of these amounts irrespective of the number of providers charging][the median of these amounts, ranking them by the number of providers with which the rates were negotiated].

Thus, for example, if for a given emergency service a plan negotiated a rate of \$100 with 100 providers, a rate of \$125 with one provider, and a rate of \$150 with one provider, the median would be [\$125 or \$100, depending upon which approach is used to determine the median].

Following the commonly accepted definition of median, if there are an even number of amounts, the median is the average of the middle two. (Cost sharing imposed with respect to the participant, beneficiary or enrollee would be deducted from this amount before determining the greatest of the three amounts.)

Although a plan or health insurance coverage is generally not constrained by the requirements of PHS Act section 2719A for cost-sharing requirements other than copayments or coinsurance, these interim final regulations include an anti-abuse rule with respect to such other cost-sharing requirements so that the purpose of limiting copayments and coinsurance for emergency services to the in-network rate cannot be thwarted by manipulation of these other cost-sharing requirements. Accordingly, any other cost-sharing requirement, such as a deductible or out-of-pocket maximum, may be imposed with respect to out-of-network emergency services if the cost-sharing requirement generally applies to out-of-network benefits.

Specifically, a deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. Similarly, if an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services. A plan or health insurance coverage could fashion these other cost-sharing requirements so that a participant, beneficiary, or enrollee is required to pay less for emergency services than for general out-of-network services; the anti-abuse rule merely prohibits a plan or health insurance coverage from fashioning such rules so that a participant, beneficiary, or enrollee is required to pay more for emergency services than for general out-of-network services.

In applying the rules relating to emergency services, the statute and these interim final regulations define the terms emergency medical condition, emergency services, and stabilize. These terms are defined generally in accordance with their meaning under the Emergency Medical Treatment and Active Labor Act (EMTALA), section 1867 of the Social Security Act. There are, however, some minor variances from the EMTALA definitions.

Application to grandfathered health plans. The statute and these interim final regulations relating to certain patient protections do not apply to grandfathered health plans. However, other Federal or State laws related to these patient protections may apply regardless of grandfather status.

E. HHS Definitions and Non-Federal Governmental Plan Reforms

1. Definitions (45 CFR 144.103)

These interim final regulations revise the definition of “preexisting condition exclusion” to clarify that the denial of an application for coverage because of a preexisting condition in the individual health insurance market is a preexisting condition exclusion. This definition at 45

CFR 144.103 is cross-referenced in both 45 CFR 146.111(a)(1) and 45 CFR 147.108, and it applies in both the group and individual health insurance markets, and also to entities that provide coverage to Federally eligible individuals pursuant to 45 CFR Part 148.

2. Treatment of Non-Federal Governmental Plans (45 CFR 146.180)

As noted, the Affordable Care Act made numerous changes to title XXVII of the PHS Act, including to former section 2721(b)(2), which permitted the sponsor of a self-funded non-Federal governmental plan, as defined in 45 CFR 144.103, to elect to exempt the plan from certain requirements of title XXVII of the PHS Act.¹⁴ Section 1001(4) of the Affordable Care Act re-designated section 2721 as section 2735. Affordable Care Act section 1562(a)(2) amended section 2735 by adding a new subparagraph (a)(2)(E), which prohibits a sponsor of a self-funded non-Federal governmental plan from electing to exempt the plan from subparts I and II in part A of the revised title XXVII. Affordable Care Act section 1562(c)(12) then amended section 2735, including re-designating subsection (b)(2) as subsection (a)(2), and then by redesignating section 2735 as section 2722.

Subpart I (“General Reform”) contains the substance of the provisions of the original subpart 1 of part A of title XXVII of the PHS Act, including limitations on preexisting condition exclusion periods, requirements for special enrollment, and prohibitions against discriminating against individual participants and beneficiaries based on health status or genetic information. Therefore, as a result of section 2722(a)(2)(E), the sponsor of a self-funded non-Federal governmental plan cannot opt out of (elect to be exempted from) the foregoing provisions, which are now in subpart I, starting with plan years beginning on or after September 23, 2010.

¹⁴ This is referred to here as an “opt-out election.”

However, while section 2722(a)(2)(E) precludes an opt-out election with respect to the new subparts I and II of part A, an opt-out election is still permitted with respect to the provisions in subpart 2 of part A. Affordable Care Act section 1001(2) re-designated sections 2704 through 2707 (which formerly set forth the provisions relating to the Newborns' and Mothers' Health Protection Act of 1996, the Mental Health Parity Act of 1996 (as amended by the Mental Health Parity and Addiction Equity Act of 2008), the Women's Health and Cancer Rights Act of 1998, and Michelle's Law (2008)) as new sections 2725 through 2728, respectively, which are contained in a revised subpart 2, "Exclusion of Plans; Enforcement; Preemption."¹⁵ A sponsor of a self-funded non-Federal governmental plan may continue to elect to exempt its plan from the requirements of new subpart 2 (which is separate from subpart II) of part A of title XXVII since the prohibition in section 2722(a)(2)(E) does not reference subpart 2.

Affordable Care Act section 1004(a) provides that the amendments made by section 1001 are "effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act[.]" The Affordable Care Act was enacted on March 23, 2010. Therefore, the amendments made by section 1001, as further amended by subsections (a) and (c)(12) of section 1562, are effective for plan years beginning on or after September 23, 2010.

The Affordable Care Act includes no exception for plan years that are governed by a previously ratified collective bargaining agreement under which the plan sponsor has elected to exempt a self-funded non-Federal governmental plan from one or more requirements of subpart 1 (as it was designated prior to enactment of the Affordable Care Act). Section 1251 of the Affordable Care Act has special rules for "grandfathered" plans, including an exception in subsection (d) for collectively bargained plans. However, the exception only applies for "**health**

¹⁵ The Affordable Care Act created Subparts I and II of Part A, but did not remove Subpart 2. Therefore, Subpart II (Roman numeral) and Subpart 2 (Arabic numeral) are separate, coexisting subparts.

insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this Act." (Emphasis added.) New section 2722(a)(2)(B)(ii) (former section 2721(b)(2)(B)(ii)) of the PHS Act, however, provides that an opt-out election made by the sponsor of a group health plan maintained pursuant to a collective bargaining agreement remains in effect "for the term of such agreement." Since this provision was not amended by the Affordable Care Act, HHS's view is that it takes precedence over the provisions of section 1251(d) of the Affordable Care Act. Accordingly, these interim final regulations state that a group health plan that is maintained pursuant to a collective bargaining agreement that was ratified before March 23, 2010 and that has been exempted from any provision in the former Subpart 1 will not have to come into compliance with those provisions until beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement.

The sponsor of a self-funded non-federal governmental plan not maintained pursuant to a collective bargaining agreement will not be permitted to elect to opt-out of the provisions in the former subpart 1 for plan years beginning on or after September 23, 2010. Although section 1251(b) of the Affordable Care Act provides grandfathering protection for plans that existed before March 23, 2010, opt-out elections initially submitted or renewed on or after the amendment effective date of September 23, 2010 for any provision in the former subpart 1 are not subject to that protection.

In addition to revisions that reflect the changes made by the Affordable Care Act discussed above, section 146.180 is further revised to make certain changes that are unrelated to the Affordable Care Act, such as adding the requirements of Michelle's Law to the list of title

XXVII requirements set forth at section 146.180(a)(1) from which self-funded non-Federal governmental plans may be exempted, updating the address to which an opt-out election should be submitted, updating an example to reflect more recent dates, and removing outdated text.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, numerous provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective

date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Yet, the requirements in these regulations require significant lead time in order to implement.

For example, in the case of the requirement under PHS Act section 2711 prohibiting overall lifetime dollar limits, these interim final regulations require that an enrollment period be provided for an individual whose coverage ended by reason of reaching a lifetime limit no later than the first day this requirement takes effect. Preparations presumably would have to be made to put such an enrollment process in place. In the case of requirements for emergency care under PHS Act section 2719A, plans and issuers need to know how to process charges by out-of-network providers by as early as the first plan or policy year beginning on or after September 23, 2010. With respect to all the changes that would be required to be made under these interim final regulations, whether adding coverage of children with a preexisting condition under PHS Act section 2704, or determining the scope of rescissions prohibited under PHS Act section 2712, group health plans and health insurance issuers have to be able to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits, and these premiums and plan or policy changes would have to receive necessary approvals in advance of the plan or policy year in question.

Accordingly, in order to allow plans and health insurance coverage to be designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact and Paperwork Burden

[TO BE CIRCULATED SEPARATELY]

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

PRELIMINARY DISCUSSION DRAFT of 6.11.10
Not for Public Distribution

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Steven T. Miller
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved:

Michael F. Mundaca
Assistant Secretary of the Treasury (Tax Policy).

Signed this ____ day of ____, 2010.

Phyllis C. Borzi
Assistant Secretary
Employee Benefits Security Administration
Department of Labor

DRAFT

Approved: _____

Jay Angoff,

Director,

Office of Consumer Information and Insurance

Oversight.

Approved: _____

Kathleen Sebelius,

Secretary, Department of Health and Human
Services.

From: [Baum, Beth - EBSA](#)
To: [Corrigan, Dara \(HHS/OHR\)](#); [Mayhew, James A. \(CMS/CPC\)](#); [Kosin, Donald \(HHS/OGC\)](#); [Dailey, Joan \(HHS/OGC\)](#); [Stafford, Leslie \(HHS/OGC\)](#); [Weinheimer Russell E](#); [Knopf Kevin - OTP](#); [Russ Weinheimer - HOME](#); [Kevin Knopf - HOME](#); [Levin Karen](#); [Schumacher, Elizabeth - EBSA](#); [Baum, Beth - EBSA](#); [Turner, Amy - EBSA](#)
Subject: Clean Drafts
Date: Friday, June 11, 2010 6:20:09 PM
Attachments: [Pkg of 6 Reg Text 6.11.10 6pm clean.doc](#)
[Pkg of 6 Joint Preamble 6.11.10 6pm clean.doc](#)

This is what we are going to circulate internally for comment over the weekend.

The plan is to meet at 11am to start incorporating comments and send to OMB by COB Monday.

PRELIMINARY DISCUSSION DRAFT of 6.11.10

Not for Public Distribution

** This document currently represents a single “joint” DOL/IRS/HHS reg text. The final document will actually include 3 parallel regulations – one IRS regulation (26 CFR Part 54), followed by one DOL regulation (29 CFR Part 2590), followed by one HHS regulation (45 CFR Parts 144, 146, and 147). The IRS and HHS reg texts will be re-formatted to include the correct citations for their Part. In addition, DOL and IRS will delete references to requirements for issuers of individual market coverage, but will include cross-references as appropriate.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 continues to read as follows:

Authority:

29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor’s Order 6-2009, 74 FR 21524 (May 7, 2009).

Subpart B—Other Requirements

2. Section 2590.701-2 is amended by revising the definition of preexisting condition exclusion to read as follows:

§ 2590.701-2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or

individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

3. Section 2590.701-3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 2590.701-2 of this Part.

* * * * *

4. Section 2590.715-2704 is added to Subpart C to read as follows:

§ 2590.715-2704 Prohibition of preexisting condition exclusions.

(a) No preexisting condition exclusions—(1) In general. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701-2 of this Part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must

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comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704).

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13-year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13-year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the child is under 19 years of age and the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13-year-old child.

5. Section 2590.715-2711 is added to Subpart C to read as follows:

§2590.715-2711 No lifetime or annual limits.

(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual

health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage,

may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) Authority of the Secretary to grant waivers. For plan years (in the individual market, policy years) beginning before January 1, 2014, the Secretary [of Health and Human Services] may establish a program under which the requirements of this section relating to annual limits may be waived for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under this section if compliance with this section will result in a significant decrease in access to benefits under the plan or health insurance coverage or a significant increase in premiums for the plan or health insurance coverage.

(e) Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit.

(1) In general. The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits ended under a group health plan or group or individual health insurance coverage by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a limit on the dollar value of all benefits under the group health plan or group or individual health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) Notice and enrollment opportunity requirements – (i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan – or group or individual health insurance coverage – described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The notice may be provided to an employee on behalf of the employee's dependent (in the individual market, to the primary subscriber on behalf of the primary subscriber's dependent). In addition, for a group health plan or group health insurance coverage, the notice

may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an employee whose dependent is entitled to an enrollment opportunity under this paragraph (e), the obligation to provide the notice of enrollment opportunity under this paragraph (e)(2) with respect to that dependent is satisfied for both the plan and the issuer.

(3) Effective date of coverage. In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §2590.701-6(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) Examples. The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan has a lifetime limit on the dollar value of all benefits. Individual B, an employee of Y, was enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, B incurred a claim

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for benefits that exceeded the lifetime limit under Y's plan and ceased to be enrolled in the plan. On or before January 1, 2011, Y's group health plan gives B written notice of B's right to enroll in the plan, and that B can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this paragraph (e) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual D, an employee of Z, and Individual E, D's child, were enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E incurred a claim for benefits that exceeded the lifetime limit under Z's plan. D dropped family coverage but remains an employee of Z.

(ii) Conclusion. In this Example 2, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) Facts. Same facts as Example 2, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the prohibition on lifetime limits applies to all grandfathered health plans, while the prohibition on annual limits, including the special rules regarding restricted annual limits, applies to group health plans and group health insurance coverage that are grandfathered health plans, but do not apply to individual health insurance coverage that is a grandfathered health plan).

6. Section 2590.715-2712 is added to Subpart C to read as follows:

§ 2590.715-2712 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide [at least 30 days] advance notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if –

(i) The cancellation or discontinuance of coverage has only a prospective effect; or

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

(3) The rules of this paragraph (a) are illustrated by the following examples:

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Example 1. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A visited a psychologist on two occasions, six years ago. A is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's visits to the psychologist, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example 1, the plan cannot rescind A's coverage because A's failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) Facts. An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual B has coverage under the plan as a full-time employee. The employer reassigns B to a part-time position. Under the terms of the plan, B is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from B, and paying claims submitted by B. After a routine audit, the plan discovers that B no longer works at least 30 hours a week. The plan rescinds B's coverage effective as of the date that B changed from a full-time employee to a part-time employee.

(ii) Conclusion. In this Example 2, the plan cannot rescind B's coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for B prospectively, subject to other applicable Federal and State laws.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

7. Section 2590.715-2714 is amended by revising paragraphs (d) and (h) to read as follows:

(d) Uniformity irrespective of age.—(1) In general. Subject to paragraph (d)(2) of this section, the terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(2) Preexisting condition exclusions for children age 19 and older before 2014. For plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or health insurance coverage may impose a preexisting condition exclusion (consistent with the rules of section 2590.701-3 of this Part [HHS add: “in the group market”]) on children who are age 19 or older even though this is prohibited with respect to children under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

8. Section 2590.715-2716 is added to Subpart C to read as follows:

§ 2590.715-2716 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code (prohibiting discrimination in favor of highly compensated individuals under a self-insured medical expense reimbursement plan as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-insured plan) under this section as if the group health plan were a self-insured medical expense reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the rules prohibiting discrimination in favor of highly compensated individuals by insured group health plans do not apply to grandfathered health plans).

9. Section 2590.715-2719A is added to Subpart C to read as follows:

§ 2590.715-2719A Patient protections.

(a) Choice of health care professional – (1) Designation of primary care provider—(i) In general. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) Example. The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) Facts. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any participating primary care provider who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan

designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) Conclusion. In this Example, the plan has satisfied the requirements of paragraph (a) of this section.

(2) Designation of pediatrician as primary care provider—(i) In general. If a group health plan or health insurance issuer offering group or individual health insurance coverage requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) Construction. Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) Examples. The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An HMO designates for each enrollee a physician who specializes in internal medicine to serve as the primary care provider for the enrollee and the enrollee's family. Enrollee A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

(ii) Conclusion. In this Example 1, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

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Example 2. (i) Facts. Same facts as Example 1, except that A takes A's child to B for treatment of the child's severe peanut allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access. A group health plan or health insurance issuer offering group or individual health insurance coverage described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care and is not limited to a physician.

(B) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services,

pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) Application of paragraph. A group health plan or health insurance issuer offering group or individual health insurance coverage is described in this paragraph if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) Construction. Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) Examples. The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(ii) Conclusion. In this Example 1, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) Facts. Same facts as Example 1 except that A seeks gynecological services from C, an out-of-network provider.

(ii) Conclusion. In this Example 2, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) Facts. Same facts as Example 1 except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(ii) Conclusion. In this Example 3, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for a scheduled cesarean section.

(ii) Conclusion. In this Example 4, the plan requirement for prior authorization before providing benefits for a scheduled cesarean section does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to services for treatments, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) Notice of right to designate a primary care provider. (i) In general. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights –

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, that any participating physician who specializes in pediatrics as the child's primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) Timing. In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) Model language. The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

Because [name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider, you have the right to designate any primary care provider who participates in the network of [name of plan or coverage] and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the plan administrator at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, insert:

If you have a child who is enrolled in [name of group health plan or health insurance issuer], you have the right to designate any pediatrician who participates in the network of [plan or coverage] and who is available to accept your child as your child's primary care provider. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one.] For information on how to select a

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pediatrician, and for a list of the participating pediatricians, contact the plan administrator at [insert contact information].

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary or enrollee of a primary care provider, insert:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain obstetrical or gynecological care from a health care professional who specializes in obstetrics or gynecology and who participates in the network of [name of group health plan or issuer]. Such a health care professional, however, may be required to comply with certain procedures required by [name of group health plan or issuer] including obtaining prior authorization for certain services, following a pre-approved treatment plan, or for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the plan administrator at [insert contact information].

(b) Coverage of emergency services.—(1) Scope. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) General rules. A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner –

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than –

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code; or

(C) Applicable cost sharing.

(3) Cost-sharing requirements – (i) Copayments and coinsurance. Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is

[the median of these amounts irrespective of the number of providers charging][the median of these amounts, ranking them by the number of providers with which the rates were negotiated], excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) Other cost sharing. Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) Examples. The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to services in an emergency department of a hospital.

Example 1. (i) Facts. A group health plan imposes a 25 percent coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of

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network. If a covered individual provides notice to the plan within two business days after the day an individual receives screening or treatment in an emergency department, the plan reduces the coinsurance rate to 15 percent.

(ii) Conclusion. In this Example 1, the requirement to provide notice in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required notice before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a \$60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) Conclusion. In this Example 2, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it receive notification rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) Facts. A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers there are five amounts: \$85, \$100, \$110, \$120, and \$150. Under the agreement, the plan agrees to pay the providers 80 percent of the agreed amount, with the individual receiving the service responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 3, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$110 (\$88).

Example 4. (i) Facts. Same facts as Example 3. Subsequently, the plan adds a provider to its network and agrees to pay the provider 80 percent of \$170 for the emergency service, with the individual responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 4, the median amount among those agreed to for the emergency service is \$115. (Because there is no one middle amount among \$85, \$100, \$110, \$120, \$150, and \$170, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$115 (\$92).

Example 5. (i) Facts. Same facts as Example 4. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the

service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50 percent of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is \$116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, would be \$80.

(ii) Conclusion. In this Example 5, the plan is responsible for paying \$92.80, 80 percent of \$116. The median amount among those agreed to for the emergency service is \$115 and the amount the plan would pay is \$92 (80 percent of \$115); the amount calculated using the same method the plan uses to determine payments for out-of-network services -- \$116 -- excluding the in-network 20 percent coinsurance, is \$92.80; and the Medicare payment is \$80. Thus, the greatest amount is \$92.80. The individual is responsible for the remaining \$32.20 charged by the out-of-network provider.

Example 6. (i) Facts. Same facts as Example 5. The group health plan generally imposes a \$250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of network.

(ii) Conclusion. In this Example 6, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network.

(4) Definitions. The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her

unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions, and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) Emergency services. The term emergency services means, with respect to an emergency medical condition –

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) Stabilize. The term to stabilize, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to all grandfathered health plans).

10. Section 146.180 is amended as follows:

- A. Revising paragraph (a)(1).
- B. Adding a new paragraph (a)(2).
- C. Renumbering paragraphs (a)(2), (a)(3) and (a)(4) as (a)(3), (a)(4) and (a)(5), respectively.

- D. Replacing “2706” with “2727” each place it appears in paragraph (a)(1)(i)(F) and in Example 1 of paragraph (a)(3) (previously designated as (a)(2)).
- E. Making a conforming change to paragraph (a)(4)(i) (previously designated as (a)(3)(i)).
- F. Updating paragraph (c) to reflect the current address to which exemption elections may be mailed and providing a facsimile number to which elections may be faxed as an alternative to mailing elections.
- G. Removing the outdated parenthetical reference to § 146.125(a)(2) in paragraph (f)(2)(ii).
- H. Making a conforming change to paragraph (f)(3)(i).
- I. Adding a conforming sentence at the end of Example 1 in paragraph (h)(4)(i).
- J. Updating Example 4 in paragraph (i)(2)(iv).

The revisions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) Requirements subject to exemption—(1) Non-collectively bargained plans. (i) Plan years commencing before September 23, 2010. A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), for plan years commencing before September 23, 2010, from any or all of the following requirements:

- (A) Limitations on preexisting condition exclusion periods described in § 146.111.
- (B) Special enrollment periods for individuals and dependents described in § 146.117.
- (C) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements in § 146.121(a)(1)(vi) and § 146.122 that prohibit discrimination with respect to genetic information.
- (D) Standards relating to benefits for mothers and newborns described in § 146.130.

(E) Parity in the application of certain limits to mental health and substance use disorder benefits described in § 146.136.

(F) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2727 of the PHS Act.

(G) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(ii) Plan years beginning on or after September 23, 2010. A sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan for plan years beginning on or after September 23, 2010, only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) or (G). With respect to those plan years, the notices required by paragraph (f) of this section must reflect the limitations set forth in this paragraph (a)(1)(ii).

(iii) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1)(i). The plan year commences September 1 each year. The plan is not subject to the limitations of paragraph (a)(1)(ii) until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(iv) Example 2. Same facts as in Example 1, except the plan year commences October 1 each year. The plan is subject to the limitations of paragraph (a)(1)(ii) beginning with the plan year that commences on October 1, 2010. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(2) Collectively bargained plans. (i) Special rule. Without regard to paragraph (b)(2) of this section, a group health plan that is governed by a collective bargaining agreement that was ratified before March 23, 2010, is subject to the limitations set forth in paragraph (a)(1)(ii) beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement. The notices required by paragraph (f) of this section, with respect to the first plan year subject to the limitations of paragraph (a)(1)(ii), must reflect those limitations.

(ii) Example. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1)(i) of this section. The collective bargaining agreement applies to five plan years, October 1, 2007 through September 30, 2012. For the plan year that commences on October 1, 2012, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1)(i)(A), (B) and (C). Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from one or more of the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(3) Limitations. * * *

(A) Example 1. A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

* * *

(4) Stop-loss or excess risk coverage. For purposes of this section—(i) Subject to paragraph (a)(4)(ii), * * *

(5) Construction. * * *

* * * * *

(c) Mailing address. The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Medicare Enrollment and Appeals Group, CM, ATTN: HIPAA Opt-Out, 7500 Security Boulevard, C2-12-16, Baltimore, MD 21244-1850. Alternatively, the plan sponsor may fax the exemption election to 410-786-8001.

* * * * *

(f) * * *

(2) * * *

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, * * *

(3) * * *

(i) The specific requirements described in paragraphs (a)(1) or (a)(2) of this section, as applicable, from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

* * * * *

(h) * * *

(4) * * *

(i) Example 1. (A) * * *

(B) * * * However, regarding plan years that begin on or after September 23, 2010, the plan sponsor no longer can elect to exempt its plan from prohibitions against enrollment discrimination based on health status-related factors.

* * *

(i) * * *

(2) * * *

(iv) Example 4: A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from the requirements of paragraph (a)(1)(i)(E) of this section. The collective bargaining agreement applies to five plan years, 2007 through 2011. For the

first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2007 through December 31, 2011. Prior to the dissemination of the annual notice for the 2010 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2007 through December 31, 2011. Accordingly, CMS would not invalidate the election for the 2010 plan year.

* * * * *

[Billing Codes: 4830-01-P; 4510-29-P; 4120-01-P]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 54 and 602

TD

RIN 1545-BJ61

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB43

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

OCHIO-XXXX-IFC

45 CFR Parts 144, 146, and 147

RIN XXXX-XXXX

**Interim Final Rules under the Patient Protection and Affordable Care Act Regarding
Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Prohibition on
Discrimination in Favor of the Highly Compensated, Patient Protections, and Non-Federal
Governmental Plans**

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits
Security Administration, Department of Labor; Office of Consumer Information and Insurance
Oversight, Department of Health and Human Services.

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ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, prohibition on discrimination in favor of highly compensated individuals, patient protections, and non-federal governmental plans.

DATES: Effective date. These interim final regulations are effective on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Comment date. Comments are due on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Applicability date. These interim final regulations generally apply to group health plans and group health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**. These interim final regulations generally apply to individual health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines.

No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB43, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Email: [E-OHPSCA\[XXXX\].EBSA@dol.gov](mailto:E-OHPSCA[XXXX].EBSA@dol.gov).

- Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: RIN 1210-AB43.

Comments received by the Department of Labor will be posted without change to www.regulations.gov and www.dol.gov/ebsa, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCHIO-9991-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.
2. By regular mail. You may mail written comments to the following address ONLY:
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services,

Attention: OCIO-9991-IFC,

P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services,

Attention: OCIO-9991-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to

leave their comments in the OCIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the

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headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-120399-10, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: CC:PA:LPD:PR (REG-120399-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-120399-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786-1565.

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's website (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for

consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp) and information on health reform can be found at <http://www.healthreform.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of part A of title XXVII of the PHS Act applicable under ERISA and the Code to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if those provisions of the PHS Act were included in ERISA and the Code. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The

¹ The term “group health plan” is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term “health plan”, as used in other provisions of title I of the Affordable Care Act. The term “health plan” does not include self-insured group health plans.

preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of the Affordable Care Act are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers stricter requirements than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations implementing the revised PHS Act sections 2701 through 2719A in several phases. The first publication in this series was a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). The second publication was interim final regulations implementing PHS Act section 2714 (requiring dependent coverage of children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third publication was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on June 17, 2010 (75 FR XXXXX). These interim final regulations are being published to implement PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), 2716 (prohibiting discrimination in favor of highly compensated individuals), 2719A (regarding patient protections), and 2722 (regarding the application of the Affordable Care Act provisions to non-

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

Federal governmental plans). PHS Act section 2704 generally is effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014. However, with respect to enrollees, including applicants for enrollment, who are under 19 years of age, PHS Act section 2704 is effective for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.³ The rest of these provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

II. Overview of the Regulations

A. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815-2704T, 29 CFR 2590.715-2704, 45 CFR 147.108)

Section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA⁴ rules relating to preexisting condition exclusions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under certain circumstances. The Affordable Care Act provision prohibits any preexisting condition exclusions imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1,

³ Section 1255 of the Affordable Care Act. See also section 10103(e)-(f) of the Affordable Care Act.

⁴ HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

HIPAA generally defines a preexisting condition exclusion⁵ as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

The protections in the new PHS Act section 2704 generally apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014. The Affordable Care Act provides, however, that these protections apply with respect to enrollees under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. An enrollee under age 19 thus could not be denied benefits based on a preexisting condition. In order for an individual to receive the same protection that applies in the case of such an enrollee, the individual similarly could not be denied benefits (through denial of enrollment or denial of specific benefits) based on a preexisting condition. Thus, for plan years (in the individual market, for policy years) beginning on or after September 23, 2010, PHS Act section 2704 protects individuals under age 19 with a preexisting condition from being denied coverage under a plan or health insurance coverage (through denial of enrollment or denial of specific benefits) based on the preexisting condition.

⁵ Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1); after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1). See also ERISA section 701(b)(1) and Code section 9801(b)(1).

These interim final regulations do not change the HIPAA rule that a plan's or issuer's exclusion of benefits for a condition from the plan or policy regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. This point is still relevant for these interim final regulations and is illustrated with examples in the HIPAA regulations on preexisting condition exclusions.⁶ (Other requirements of Federal or State law, however, may prohibit certain benefit exclusions.)

The interim final regulations under PHS Act section 2714 (relating to the continuation of dependent coverage until a child turns age 26) (75 FR 27122, May 13, 2010) provide that the terms of a plan or policy for dependent coverage cannot vary based on the age of a child, except for children age 26 or older. These interim final regulations amend those regulations to clarify that, for plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or policy may impose a preexisting condition exclusion (consistent with the rules of 26 CFR 54.9801-3, 29 CFR 2590.701-3, and 45 CFR 146.111) on children who are age 19 or older even though this is prohibited with respect to children under age 19.

Application to grandfathered health plans. Under the statute and these interim final regulations, a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704. See 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 regarding status as a grandfathered health plan.

B. PHS Act Section 2711, Lifetime and Annual Limits (26 CFR 54.9815-2711T, 29 CFR 2590.715-2711, 45 CFR 147.126)

⁶ See Examples 6, 7, and 8 in 26 CFR 54.9801-3(a)(1)(ii), 29 CFR 701-3(a)(1)(ii), 45 CFR 146.111(a)(1)(ii).

Section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits. However, these interim final regulations provide that the annual limit rules do not apply to health flexible spending arrangements.⁷

The statute also allows “restricted annual limits” with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. In addition, the statute provides that, with respect to benefits that are not essential health benefits, a plan or issuer may impose annual or lifetime per-individual limits on specific covered benefits. Rather than provide a definition of “essential health benefits,” these interim final regulations cross-reference section 1302(b) of the Affordable Care Act and applicable regulations.⁸

These interim final regulations clarify that the prohibition under PHS Act section 2711 does not prevent a plan or issuer from excluding all benefits for a condition, but if any benefits are provided for a condition, then the requirements of the rule apply. Therefore, an exclusion of all benefits for a condition is not considered to be an annual or lifetime dollar limit.

The statute and these interim final regulations provide that for plan years (in the individual market, policy years) beginning before January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may establish a restricted annual limit on the dollar value of essential health benefits. The statute provides that in defining the term restricted annual limit, the Departments ensure that access to needed services is made available with a minimal impact on premiums.

⁷ Section 9005 of the Affordable Care Act specifically limits the annual amount of salary reduction contributions for health flexible spending arrangements.

⁸ Regulations under section 1302(b) of the Affordable Care Act have not yet been issued.

In establishing the restricted annual limit, the Departments considered several factors: (1) the current use of annual limits in the group and individual market; (2) the average premium impact of imposing different annual limits on the individual, small group, and large group markets; (3) the number of individuals who will continue to have annual medical expenses that exceed an annual limit; and (4) the possibility that a plan or issuer would switch to an annual limit when lifetime limits are prohibited.

In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, these interim final regulations adopt a three-year phased approach for restricted annual limits. Under these interim final regulations, annual limits on the dollar value of benefits that are essential health benefits may not be less than the following amounts for plan years (in the individual market, policy years) beginning before January 1, 2014:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, \$750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, \$1.25 million; and
- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2 million.

As these are minimums for plan years (in the individual market, policy years) beginning before 2014, plans or issuers may always use higher annual limits or impose no limits. Plans and policies with plan or policy years that begin between September 23 and December 31 have more than one plan or policy year under which the \$2 million minimum annual limit is available;

however, a plan or policy generally may not impose an annual limit for a plan year beginning after December 31, 2013.

The minimum annual limits for plan or policy years beginning before 2014 apply on an individual-by-individual basis. Thus, any overall annual dollar limit on benefits applied to families may not operate to deny a covered individual the minimum annual benefits for the plan year (in the individual market, policy year). These interim final regulations clarify that, in applying annual limits for plan years (in the individual market, policy years) beginning before January 1, 2014, the plan or health insurance coverage may only take into account essential health benefits.

Although the restricted annual limits provided in these interim final regulations are designed to ensure, in the vast majority of cases, that individuals would have access to needed services with a minimal impact on premiums, the Departments recognize that for a small minority of plans or health insurance coverage, compliance with the annual limit requirement prescribed in these interim final regulations could have the effect of either denying access to needed services or having more than a minimal impact on premiums. In order to avoid having individuals with such coverage be denied access to needed services or experience more than a minimal impact on premiums, these interim final regulations provide for the Secretary [of Health Human Services] to establish a program under which the requirements relating to annual limits may be waived if compliance with these interim final regulations will result in a significant decrease in access to benefits or a significant increase in premiums. The Departments request comments on the scope of the program. For example, should both insured and self-insured coverage be eligible for the program? Should certain low-cost benefit plans (sometimes referred to as mini-med plans) or health reimbursement arrangements be eligible? Should the waiver

apply to the entire period before January 1, 2014 or be granted on a plan-year-by-plan-year basis?

These interim final regulations require that individuals who reached a lifetime limit under a plan or health insurance coverage and are otherwise still eligible under the plan or health insurance coverage are provided with a notice that the lifetime limit no longer applies. If such an individual is no longer enrolled in the plan or health insurance coverage, these interim final regulations also provide an enrollment (in the individual market, reinstatement) opportunity for such individuals. In the individual market, this reinstatement opportunity does not apply to individuals who reached their lifetime limits in individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in a family policy in the individual market while other family members remain in the coverage. These notices and the enrollment opportunity must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

Application to grandfathered health plans. The statute and these interim final regulations relating to the prohibition on lifetime limits apply to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the prohibition on annual limits, including the special rules regarding restricted annual limits for plan years beginning before January 1, 2014, apply to group health plans and group health insurance

coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage.⁹

C. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815-2712T, 29 CFR 2590.715-2712, 45 CFR 147.128)

PHS Act section 2712 provides rules regarding rescissions of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard applies to all rescissions, whether in the group or individual insurance market, or self-insured coverage. These rules also apply regardless of any contestability period of the plan or issuer.

These interim final regulations include several clarifications regarding the standards for rescission. First, these interim final regulations clarify that the rules of PHS Act section 2712 apply whether the rescission applies to a single individual or an entire group of individuals. Thus, for example, if an issuer attempted to rescind coverage of an entire employer group based on the actions of an individual within the group, the standards of these interim final regulations would apply. Second, these interim final regulations clarify that the rules of PHS Act section 2712 apply to representations made by the individual or a person seeking coverage on behalf of

⁹ Note also that the regulations issued under section 1251 of the Affordable Care Act include a rule relating to retention of status as a grandfathered health plan based on changes to annual limits. Under those regulations, three different situations are addressed. First, a plan or health insurance coverage that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits. Second, a plan or health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010. Third, a plan or health insurance coverage that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

the individual. Thus, if a plan sponsor seeks coverage from an issuer for an entire employment-based group and makes representations, for example, regarding the prior claims experience of the group, the standards of these interim final regulations would also apply. Finally, PHS Act section 2712 refers to acts or practices that constitute fraud. These interim final regulations clarify that, to the extent that an omission constitutes fraud, that omission would permit the plan or issuer to rescind coverage under this section. An example in these interim final regulations illustrates the application of the rule to misstatements of fact that are inadvertent.

For purposes of these interim final regulations, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission, and neither is a cancellation or discontinuance of coverage that is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

PHS Act section 2712 adds a new advance notice requirement when coverage is rescinded where still permissible. Specifically, the second sentence in section 2712 provides that coverage may not be cancelled unless prior notice is provided, and then only as permitted under PHS Act sections 2702(c) and 2742(b). Under these interim final regulations, even if prior notice is provided, rescission is only permitted in cases of fraud or an intentional

misrepresentation of a material fact as permitted under the cited provisions.¹⁰ While this reference appears redundant, it is consistent with the first sentence.

These interim final regulations provide that a group health plan, or a health insurance issuer offering group health insurance coverage, must provide [at least 30 days] advance notice to an individual before coverage may be rescinded.¹¹ The notice must be provided regardless of whether the rescission is of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group.

These interim final regulations also clarify that other requirements of Federal or State law may apply in connection with a rescission of coverage.

Application to grandfathered health plans. The rules regarding rescissions and advance notice apply to all grandfathered health plans.

D. PHS Act Section 2716, Prohibiting Discrimination in Favor of Highly Compensated Individuals (26 CFR 54.9815-2716T, 29 CFR 2590.715-2716, 45 CFR 147.132)

PHS Act section 2716 and these interim final regulations incorporate the nondiscrimination rules of section 105(h) of the Code and apply them to group health plans that are not self-insured plans. Section 105(h) generally prohibits self-insured medical reimbursement plans from discriminating in favor of highly compensated individuals in eligibility classifications or in benefits. Section 105(b) of the Code generally excludes from an employee's income (otherwise subject to federal income taxation) amounts received as

¹⁰ The reference to section 2702(c) appears to be incorrect. After the amendments made by the Affordable Care Act, PHS Act section 2702(c) addresses network requirements for guaranteed availability of coverage. It seems more likely that the intended cross-reference is to new PHS Act section 2703(b), relating to nonrenewal of coverage in the group market, which corresponds to the other cross-reference, in PHS Act section 2742(b), to nonrenewal of coverage in the individual market. Both these provisions contain the fraud and intentional misrepresentation of material fact standard included in the first sentence of section 2712. In order to avoid confusion, these interim final regulations apply the fraud and misrepresentation standard found in sections 2703(b) and 2742(b).

¹¹ Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

reimbursement of medical care expenses for the employee or the employee's spouse, dependents, or children who have not attained age 27 by the end of the taxable year. If a self-insured medical reimbursement plan does not comply with the requirements of section 105(h), the general exclusion from income (and hence, from federal income taxation) under section 105(b) does not apply with respect to highly compensated individuals. Highly compensated individuals are defined in section 105(h).

PHS Act section 2716 and these interim final regulations incorporate the substantive nondiscrimination requirements of Code section 105(h) but not the tax sanctions. An insured group health plan failing to comply with the nondiscrimination requirements of Code section 105(h) is subject to the sanctions and remedies that generally apply for a plan failing to comply with the requirements of chapter 100 of the Code (generally, an excise tax of \$100 per day per individual discriminated against for each day the plan does not comply with the requirement), part 7 of ERISA (a civil action to enjoin a noncompliant act or practice or for appropriate equitable relief), or title XXVII of the PHS Act (civil money penalties of \$100 per day per individual discriminated against for each day the plan does not comply with the requirement). Thus, if a self-insured plan fails to comply with Code section 105(h), highly compensated individuals lose a tax benefit; if an insured group health plan fails to comply with Code section 105(h), the plan is subject to a civil action to compel it to provide nondiscriminatory benefits and the plan or plan sponsor is subject to an excise tax or civil money penalty of \$100 per day per individual discriminated against. Rather than restate the rules under section 105(h) of the Code, these interim final regulations incorporate by reference those rules and applicable regulations.

Questions have arisen as to how this rule applies to health insurance policies purchased by employers for employees on an individual-by-individual basis. That is, do these rules apply if

an employer buys an individual policy for a highly compensated employee, separate from the health coverage offered to other employees? The Departments proposed rules on December 30, 2004 (69 FR 78800) that provide, among other things, that if a principal purpose of establishing separate plans is to evade any requirement of law, then the separate plans will be considered a single plan to the extent necessary to prevent the evasion. The Departments expect to finalize these rules soon.

The regulations under section 105(h) of the Code, prohibiting discrimination in favor of highly compensated individuals under self-insured medical expense reimbursement plans, were issued in _____. The Department of the Treasury and the IRS request comments on what additional guidance relating to the application of section 105(h) would be helpful, especially as applied to insured group health plans.

Application to grandfathered health plans. The rules prohibiting discrimination in favor of highly compensated individuals by insured group health plans do not apply to grandfathered health plans (but the rules of Code section 105(h) continue to apply to self-insured plans).

D. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815-2719AT, 29 CFR 2590.715-2719A, 45 CFR 147.138)

Section 2719A of the PHS Act imposes, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of a health care professional and requirements relating to benefits for emergency services. The three requirements relating to the choice of health care professional apply only with respect to a plan or health insurance coverage with a network of providers.¹² Thus, a plan or issuer that has not negotiated with any provider for the delivery of health care but merely reimburses individuals

¹² The statute and these interim final regulations refer to providers both in terms of their participation and in terms of a network. In both situations, the intent is to refer to a provider that has a contractual relationship or other arrangement with a plan or issuer.

covered under the plan for their receipt of health care is not subject to the requirements relating to the choice of a health care professional. However, such plans or health insurance coverage are subject to requirements relating to benefits for emergency services. These interim final regulations reorder the statutory requirements so that all three of the requirements relating to the choice of a health care professional are together and add a notice requirement for those three requirements.

1. Choice of Health Care Professional

The statute and these interim final regulations provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In accordance with paragraph (a)(4) of these interim final regulations, the plan or issuer must provide a notice informing each participant (or in the individual market, the primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

The statute and these interim final regulations impose a requirement for the designation of a pediatrician similar to the requirement for the designation of a primary care physician. Specifically, if a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the notice requirements of paragraph (a)(4) of

these interim final regulations. The general terms of the plan or health insurance coverage regarding pediatric care otherwise are unaffected, including any exclusions with respect to coverage of pediatric care.

The statute and these interim final regulations also provide rules for a group health plan, or a health insurance issuer offering group or individual health insurance coverage, that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. In such a case, the plan or issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology. The plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. Nothing in these interim final regulations precludes the plan or issuer from requiring an in-network obstetrical or gynecological provider to otherwise adhere to policies and procedures regarding referrals, prior authorization for treatments, and the provision of services pursuant to a treatment plan approved by the plan or issuer. The plan or issuer must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the professional who specializes in obstetrics or gynecology as the authorization of the primary care provider. For this purpose, a health care professional who specializes in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care, and is not limited to a physician.

The general terms of the plan or coverage regarding exclusions of coverage with respect to obstetrical or gynecological care are otherwise unaffected. These interim final regulations do not preclude the plan or issuer from requiring that the obstetrical or gynecological provider notify the primary care provider or the plan or issuer of treatment decisions.

When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization. Accordingly, these interim final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. Model language is provided in these interim final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

2. Emergency Services

If a plan or health insurance coverage provides any benefits with respect to emergency services in an emergency department of a hospital, the plan or issuer must cover emergency services in a way that is consistent with these interim final regulations. These interim final regulations require that a plan providing emergency services must do so without any prior authorization (even if the emergency services are provided out of network) and without regard to whether the health care provider furnishing the emergency services is an in-network provider with respect to the services. The emergency services must be provided without regard to any other term or condition of the plan or health insurance coverage other than the exclusion or

coordination of benefits, an affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code, or applicable cost-sharing requirements. For a plan or health insurance coverage with a network of providers that provides benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or limitations that apply to in-network emergency services.

Additionally, for a plan or health insurance coverage with a network, these interim final regulations provide rules for cost-sharing requirements for emergency services that are expressed as a copayment amount or coinsurance rate, and other cost-sharing requirements. Cost-sharing requirements expressed as a copayment amount or coinsurance rate imposed for out-of-network emergency services cannot exceed the cost-sharing requirements that would be imposed if the services were provided in-network. A plan or issuer satisfies this requirement if it provides benefits for out-of-network emergency services in an amount equal to the greatest of three possible amounts—

- (1) The amount negotiated with in-network providers for the emergency service furnished;
- (2) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges); or
- (3) The amount that would be paid under Medicare for the emergency service.¹³

Each of these three amounts is calculated excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

¹³ As of the date of publication of these interim final regulations, these rates are available to the public at <http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf>.

In connection with determining the first amount above, for plans and health insurance coverage under which there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the amount is disregarded, meaning that the greatest amount is going to be either the out-of-network amount or the Medicare amount.

Additionally, with respect to determining the first amount, if a plan or issuer has more than one negotiated amount with in-network providers for a particular emergency service, the amount is [the median of these amounts irrespective of the number of providers charging][the median of these amounts, ranking them by the number of providers with which the rates were negotiated].

Thus, for example, if for a given emergency service a plan negotiated a rate of \$100 with 100 providers, a rate of \$125 with one provider, and a rate of \$150 with one provider, the median would be [\$125 or \$100, depending upon which approach is used to determine the median].

Following the commonly accepted definition of median, if there are an even number of amounts, the median is the average of the middle two. (Cost sharing imposed with respect to the participant, beneficiary or enrollee would be deducted from this amount before determining the greatest of the three amounts.)

Although a plan or health insurance coverage is generally not constrained by the requirements of PHS Act section 2719A for cost-sharing requirements other than copayments or coinsurance, these interim final regulations include an anti-abuse rule with respect to such other cost-sharing requirements so that the purpose of limiting copayments and coinsurance for emergency services to the in-network rate cannot be thwarted by manipulation of these other cost-sharing requirements. Accordingly, any other cost-sharing requirement, such as a deductible or out-of-pocket maximum, may be imposed with respect to out-of-network emergency services if the cost-sharing requirement generally applies to out-of-network benefits.

Specifically, a deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. Similarly, if an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services. A plan or health insurance coverage could fashion these other cost-sharing requirements so that a participant, beneficiary, or enrollee is required to pay less for emergency services than for general out-of-network services; the anti-abuse rule merely prohibits a plan or health insurance coverage from fashioning such rules so that a participant, beneficiary, or enrollee is required to pay more for emergency services than for general out-of-network services.

In applying the rules relating to emergency services, the statute and these interim final regulations define the terms emergency medical condition, emergency services, and stabilize. These terms are defined generally in accordance with their meaning under the Emergency Medical Treatment and Active Labor Act (EMTALA), section 1867 of the Social Security Act. There are, however, some minor variances from the EMTALA definitions.

Application to grandfathered health plans. The statute and these interim final regulations relating to certain patient protections do not apply to grandfathered health plans. However, other Federal or State laws related to these patient protections may apply regardless of grandfather status.

E. HHS Definitions and Non-Federal Governmental Plan Reforms

1. Definitions (45 CFR 144.103)

These interim final regulations revise the definition of “preexisting condition exclusion” to clarify that the denial of an application for coverage because of a preexisting condition in the individual health insurance market is a preexisting condition exclusion. This definition at 45

CFR 144.103 is cross-referenced in both 45 CFR 146.111(a)(1) and 45 CFR 147.108, and it applies in both the group and individual health insurance markets, and also to entities that provide coverage to Federally eligible individuals pursuant to 45 CFR Part 148.

2. Treatment of Non-Federal Governmental Plans (45 CFR 146.180)

As noted, the Affordable Care Act made numerous changes to title XXVII of the PHS Act, including to former section 2721(b)(2), which permitted the sponsor of a self-funded non-Federal governmental plan, as defined in 45 CFR 144.103, to elect to exempt the plan from certain requirements of title XXVII of the PHS Act.¹⁴ Section 1001(4) of the Affordable Care Act re-designated section 2721 as section 2735. Affordable Care Act section 1562(a)(2) amended section 2735 by adding a new subparagraph (a)(2)(E), which prohibits a sponsor of a self-funded non-Federal governmental plan from electing to exempt the plan from subparts I and II in part A of the revised title XXVII. Affordable Care Act section 1562(c)(12) then amended section 2735, including re-designating subsection (b)(2) as subsection (a)(2), and then by redesignating section 2735 as section 2722.

Subpart I (“General Reform”) contains the substance of the provisions of the original subpart 1 of part A of title XXVII of the PHS Act, including limitations on preexisting condition exclusion periods, requirements for special enrollment, and prohibitions against discriminating against individual participants and beneficiaries based on health status or genetic information. Therefore, as a result of section 2722(a)(2)(E), the sponsor of a self-funded non-Federal governmental plan cannot opt out of (elect to be exempted from) the foregoing provisions, which are now in subpart I, starting with plan years beginning on or after September 23, 2010.

¹⁴ This is referred to here as an “opt-out election.”

However, while section 2722(a)(2)(E) precludes an opt-out election with respect to the new subparts I and II of part A, an opt-out election is still permitted with respect to the provisions in subpart 2 of part A. Affordable Care Act section 1001(2) re-designated sections 2704 through 2707 (which formerly set forth the provisions relating to the Newborns' and Mothers' Health Protection Act of 1996, the Mental Health Parity Act of 1996 (as amended by the Mental Health Parity and Addiction Equity Act of 2008), the Women's Health and Cancer Rights Act of 1998, and Michelle's Law (2008)) as new sections 2725 through 2728, respectively, which are contained in a revised subpart 2, "Exclusion of Plans; Enforcement; Preemption."¹⁵ A sponsor of a self-funded non-Federal governmental plan may continue to elect to exempt its plan from the requirements of new subpart 2 (which is separate from subpart II) of part A of title XXVII since the prohibition in section 2722(a)(2)(E) does not reference subpart 2.

Affordable Care Act section 1004(a) provides that the amendments made by section 1001 are "effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act[.]" The Affordable Care Act was enacted on March 23, 2010. Therefore, the amendments made by section 1001, as further amended by subsections (a) and (c)(12) of section 1562, are effective for plan years beginning on or after September 23, 2010.

The Affordable Care Act includes no exception for plan years that are governed by a previously ratified collective bargaining agreement under which the plan sponsor has elected to exempt a self-funded non-Federal governmental plan from one or more requirements of subpart 1 (as it was designated prior to enactment of the Affordable Care Act). Section 1251 of the Affordable Care Act has special rules for "grandfathered" plans, including an exception in subsection (d) for collectively bargained plans. However, the exception only applies for "**health**

¹⁵ The Affordable Care Act created Subparts I and II of Part A, but did not remove Subpart 2. Therefore, Subpart II (Roman numeral) and Subpart 2 (Arabic numeral) are separate, coexisting subparts.

insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this Act." (Emphasis added.) New section 2722(a)(2)(B)(ii) (former section 2721(b)(2)(B)(ii)) of the PHS Act, however, provides that an opt-out election made by the sponsor of a group health plan maintained pursuant to a collective bargaining agreement remains in effect "for the term of such agreement." Since this provision was not amended by the Affordable Care Act, HHS's view is that it takes precedence over the provisions of section 1251(d) of the Affordable Care Act. Accordingly, these interim final regulations state that a group health plan that is maintained pursuant to a collective bargaining agreement that was ratified before March 23, 2010 and that has been exempted from any provision in the former Subpart 1 will not have to come into compliance with those provisions until beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement.

The sponsor of a self-funded non-federal governmental plan not maintained pursuant to a collective bargaining agreement will not be permitted to elect to opt-out of the provisions in the former subpart 1 for plan years beginning on or after September 23, 2010. Although section 1251(b) of the Affordable Care Act provides grandfathering protection for plans that existed before March 23, 2010, opt-out elections initially submitted or renewed on or after the amendment effective date of September 23, 2010 for any provision in the former subpart 1 are not subject to that protection.

In addition to revisions that reflect the changes made by the Affordable Care Act discussed above, section 146.180 is further revised to make certain changes that are unrelated to the Affordable Care Act, such as adding the requirements of Michelle's Law to the list of title

XXVII requirements set forth at section 146.180(a)(1) from which self-funded non-Federal governmental plans may be exempted, updating the address to which an opt-out election should be submitted, updating an example to reflect more recent dates, and removing outdated text.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, numerous provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective

date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Yet, the requirements in these regulations require significant lead time in order to implement.

For example, in the case of the requirement under PHS Act section 2711 prohibiting overall lifetime dollar limits, these interim final regulations require that an enrollment period be provided for an individual whose coverage ended by reason of reaching a lifetime limit no later than the first day this requirement takes effect. Preparations presumably would have to be made to put such an enrollment process in place. In the case of requirements for emergency care under PHS Act section 2719A, plans and issuers need to know how to process charges by out-of-network providers by as early as the first plan or policy year beginning on or after September 23, 2010. With respect to all the changes that would be required to be made under these interim final regulations, whether adding coverage of children with a preexisting condition under PHS Act section 2704, or determining the scope of rescissions prohibited under PHS Act section 2712, group health plans and health insurance issuers have to be able to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits, and these premiums and plan or policy changes would have to receive necessary approvals in advance of the plan or policy year in question.

Accordingly, in order to allow plans and health insurance coverage to be designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact and Paperwork Burden

[TO BE CIRCULATED SEPARATELY]

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

PRELIMINARY DISCUSSION DRAFT of 6.11.10
Not for Public Distribution

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Steven T. Miller
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved:

Michael F. Mundaca
Assistant Secretary of the Treasury (Tax Policy).

Signed this ____ day of ____, 2010.

Phyllis C. Borzi
Assistant Secretary
Employee Benefits Security Administration
Department of Labor

DRAFT

Approved: _____

Jay Angoff,

Director,

Office of Consumer Information and Insurance

Oversight.

Approved: _____

Kathleen Sebelius,

Secretary, Department of Health and Human
Services.

From: [Baum, Beth - EBSA](#)
To: [Corrigan, Dara \(HHS/OHR\)](#); [Kosin, Donald \(HHS/OGC\)](#); [Mayhew, James A. \(CMS/CPC\)](#); [Knopf, Kevin - OTP](#); [Russell, E. Weinheimer@IRSCOUNSEL.TREAS.GOV](#); [Levin, Karen](#)
Cc: [Turner, Amy - EBSA](#); [Schumacher, Elizabeth - EBSA](#)
Subject: FW: Emailing: Pkg of 6 Reg Text 6.10.10 130pm clean
Date: Thursday, June 10, 2010 5:44:46 PM
Attachments: [Pkg of 6 Joint Preamble 6.10.10 10 am.doc](#)
[Pkg of 6 Reg Text 6.10.10 130pm clean.doc](#)

<<Pkg of 6 Reg Text 6.10.10 130pm clean.doc>> Hey everyone --

The tentative plan is to meet at 1pm tomorrow to pick up with the 6 pack, to give time to get the grandfather reg over to OFR in the morning (hopefully).

-Beth

-----Original Message-----

From: Baum, Beth - EBSA
Sent: Thursday, June 10, 2010 5:26 PM
To: 'Corrigan, Dara (HHS/ASPE)'
Subject: Emailing: Pkg of 6 Reg Text 6.10.10 130pm clean

The message is ready to be sent with the following file or link attachments:

Pkg of 6 Reg Text 6.10.10 130pm clean

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 continues to read as follows:

Authority:

29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

Subpart B—Other Requirements

2. Section 2590.701-2 is amended by revising the definition of preexisting condition exclusion to read as follows:

§ 2590.701-2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an

individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

3. Section 2590.701-3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 2590.701-2 of this Part.

* * * * *

4. Section 2590.715-2714 is amended by revising paragraph (d) to read as follows:

(d) Uniformity irrespective of age.—(1) In general. Subject to paragraph (d)(2) of this section, the terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(2) Preexisting condition exclusions for children age 19 and older before 2014. For plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or health insurance coverage may impose a preexisting condition exclusion (consistent with the rules of section 2590.701-3 of this Part) on children who are age 19 or older even though this is prohibited with respect to children under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

5. Section 2590.715-2704 is added to Subpart C to read as follows:

§ 2590.715-2704 Prohibition of preexisting condition exclusions.

(a) In general. (1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701-2 of this Part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition. (The denial of an application for coverage based on a preexisting condition exclusion also violates PHS Act section 2702 (guaranteed availability of coverage) and PHS Act section 2705 (prohibition against discrimination based on health status) for policy years beginning on or after January 1, 2014.)

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13 year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13 year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13 year-old child.

6. Section 2590.715-2711 is added to Subpart C to read as follows:

§2590.715-2711 No lifetime or annual limits.

(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) Authority of the Secretary to grant waivers. For plan years beginning before January 1, 2014, the Secretary [of Health and Human Services] may establish a program under which the requirements of this section relating to annual limits may be waived for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under this section if compliance with this section will result in a significant decrease in access to benefits under a plan or health insurance coverage or a significant increase in premiums for the plan or health insurance coverage.

(e) Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit.

Comment [b1]: Note for preamble to explain why this is different than 2714: there may be situations where, for ex, coverage under family policy has not technically ended but they hit lifetime max and cannot get benefits.

(1) In general. The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits ended under a group health plan or group or individual health insurance coverage by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a limit on the dollar value of all benefits under the group health plan or group or individual health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) Notice and enrollment opportunity requirements – (i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan – or group or individual health insurance coverage – described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. If the individual is not covered under the plan or health insurance coverage, the plan and issuer must give the individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This opportunity (including the written notice) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The notice may be provided to an employee on behalf of the employee's dependent.

In addition, the notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. If a notice satisfying the requirements of this paragraph (e)(2) is provided to an employee whose dependent is entitled to an enrollment opportunity under this paragraph (e), the obligation to provide the notice of enrollment opportunity under this paragraph (e)(2) with respect to that dependent is satisfied for both the plan and the issuer.

(3) Effective date of coverage. In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §2590.701-6(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) Examples. The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan has a lifetime

Comment [blb2]: Need to revise – these are from 2714.

limit on the dollar value of all benefits. Individual B, an employee of Y, was enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, B incurs a claim for benefits that exceeds the lifetime limit under Y's plan and ceases coverage under the plan. On or before January 1, 2011, Y's group health plan gives B written notice of B's right to enroll in the plan, and that B can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this paragraph (e) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual D, an employee of Z, and Individual E, D's child, are enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E incurs a claim for benefits that exceeds the lifetime limit under Z's plan. D drops family coverage but remains an employee of Z.

(ii) Conclusion. In this Example 2, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) Facts. Same facts as Example 2, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 4. (i) Facts. Same facts as Example 2, except that E elected COBRA continuation coverage.

(ii) Conclusion. In this Example 4, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll other than as a COBRA qualified beneficiary (and must provide, by that date, written notice of the opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

7. Section 2590.715-2712 is added to Subpart C to read as follows:

§ 2590.715-2712 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if –

(i) The cancellation or discontinuance of coverage has only a prospective effect; or

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A was treated for acne six years ago. A is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's prior treatment for acne, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example 1, the plan cannot rescind A's coverage because A's failure to disclose the prior treatment for acne was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) Facts. A group health plan provides coverage for full-time employees, defined as working at least 30 hours per week. Employees who work less than 30 hours per week do not qualify for health coverage. Individual B has coverage under the plan as a full time employee. B switches from a full-time position to a part-time position. The plan continues to provide health coverage, including collecting premiums from B and paying claims submitted by B. Subsequently, the plan is informed that B no longer works at least 30 hours a week. The plan rescinds B's coverage effective as of the date that B changed from a full-time employee to a part-time employee.

(ii) Conclusion. In this Example 2, the plan cannot rescind B's coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for B prospectively, subject to other applicable Federal and State laws.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

8. Section 2590.715-2716 is added to Subpart C to read as follows:

§ 2590.715-2716 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code that apply to self-insured medical reimbursement plans (prohibiting discrimination in favor of highly compensated individuals as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-insured plan) under this section as if the group health plan were a self-insured medical reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

9. Section 2590.715-2719A is added to Subpart C to read as follows:

§ 2590.715-2719A Patient protections.

(a) Choice of health care professional – (1) Designation of primary care provider—(i) In general. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee

of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) Example. The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) Facts. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any participating primary care provider who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) Conclusion. In this Example, the plan has satisfied the requirements of paragraph (a) of this section.

(2) Designation of pediatrician as primary care provider—(i) In general. If a group health plan or health insurance issuer offering group or individual health insurance coverage requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) Construction. Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) Examples. The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An HMO designates for each enrollee a physician who specializes in internal medicine to serve as the primary care provider for the enrollee and the enrollee's family. Enrollee A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

(ii) Conclusion. In this Example 1, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) Facts. Same facts as Example 1, except that A takes A's child to B for treatment of the child's severe peanut allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access. A group health plan or health insurance issuer offering group or individual health insurance coverage described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a

participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual who is licensed under applicable State law to provide obstetrical or gynecological care and is not limited to a physician.

(B) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) Application of paragraph. A group health plan or health insurance issuer offering group or individual health insurance coverage is described in this paragraph if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) Construction. Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) Examples. The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(ii) Conclusion. In this Example 1, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) Facts. Same facts as Example 1 except that A seeks gynecological services from C, an out-of-network provider.

(ii) Conclusion. In this Example 2, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) Facts. Same facts as Example 1 except that the group health plan requires B to inform A's designated primary care physician of treatment decisions.

(ii) Conclusion. In this Example 3, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for a scheduled cesarean section.

(ii) Conclusion. In this Example 4, the plan requirement for prior authorization before providing benefits for a scheduled cesarean section does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to services for treatments, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) Notice of right to designate a primary care provider. (i) In general. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights –

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, that any participating physician who specializes in pediatrics as the child's primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) Timing. The notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage (in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance).

(iii) Model language. The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

Because [name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider, you have the right to designate any primary care provider who participates in the network of [name of plan or coverage] who is available to accept you or your family members. [If the plan or health

insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the plan administrator at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, insert:

If you have a child who is enrolled in [name of group health plan or health insurance issuer], you have the right to designate any pediatrician who participates in the network of [plan or coverage] who is available to accept your child as your child's primary care provider. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one.] For information on how to select a pediatrician, and for a list of the participating pediatricians, contact the plan administrator at [insert contact information].

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary or enrollee of a primary care provider, insert:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain obstetrical or gynecological care from a health care professional who specializes in obstetrics or gynecology and who participates in the network of [name of group health plan or issuer]. Such a health care professional, however, may be required to comply with certain procedures required by [name of group health plan or issuer] including obtaining prior authorization for certain services, following a pre-approved treatment plan, or for making referrals. For a list of participating health care professionals who specializes in obstetrics or gynecology, contact the plan administrator at [insert contact information].

(b) Coverage of emergency services.—(1) Scope. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) General rules. A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner –

(i) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the services is a participating network provider with respect to the services;

(iii) If the services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than –

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code; or

(C) Applicable cost sharing.

(3) Cost-sharing requirements – (i) Copayments and coinsurance. Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to the participant, beneficiary, or enrollee if the services were provided in-network. A group health plan or health insurance issuer satisfies this requirement with respect to an emergency service if it provides benefits in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section.

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the amount under this paragraph (b)(3)(i)(A) is zero.

(B) The amount for the emergency service calculated using the same method the plan uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(C) The amount paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

Comment [b3]: Note for preamble: need to describe where these rates are available to the public.

(ii) Other cost sharing. Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

Comment [b4]: Notes for preamble on deductibles and OOP max: states can always be more strict, plans can always be more generous.

(iii) Examples. The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to services in an emergency department of a hospital.

Example 1. (i) Facts. A group health plan imposes a 25 percent coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual provides notice to the plan within two business days after the day an individual receives screening or treatment in an emergency department, the plan reduces the coinsurance rate to 15 percent.

(ii) Conclusion. In this Example 1, the requirement to provide notice in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required notice before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a \$60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) Conclusion. In this Example 2, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it receive notification rather than grant authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) Facts. Same facts as Example 2, except that the plan also waives the copayment where emergency services are not preauthorized if it later determines that the medical condition was an emergency medical condition as defined in this paragraph (b).

(ii) Conclusion. In this Example 3, the plan does not violate the requirements of this paragraph (b) because the plan does not impose the copayment if the individual has an emergency medical condition. Thus, there is no prior authorization requirement in order to receive coverage for an emergency medical condition.

Example 4. (i) Facts. A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers there are five amounts: \$85, \$100, \$110, \$120, and \$150. Under the agreement, the plan agrees to pay the providers 80 percent of the agreed amount, with the individual receiving the service responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 4, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$110 (\$88).

Example 5. (i) Facts. Same facts as Example 4. Subsequently, the plan adds a provider to its network and agrees to pay the provider 80 percent of \$170 for the emergency service, with the individual responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 5, the median amount among those agreed to for the emergency service is \$115. (Because there is no one middle amount among \$85, \$100, \$110, \$120, \$150, and \$170, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80 percent of \$115 (\$92).

Example 6. (i) Facts. Same facts as Example 5. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50 percent of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is \$116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, would be \$80.

(ii) Conclusion. In this Example 6, the plan is responsible for paying \$92.80, 80 percent of \$116. The median amount among those agreed to for the emergency service is \$115 and the amount the plan would pay is \$92 (80 percent of \$115); the amount calculated using the same method the plan uses to determine payments for out-of-network services -- \$116 -- excluding the in-network 20 percent coinsurance, is \$92.80; and the Medicare payment is \$80. Thus, the greatest amount is \$92.80. The individual is responsible for the remaining \$32.20 charged by the out-of-network provider.

Example 7. (i) Facts. Same facts as Example 6. The group health plan generally imposes a \$250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of network.

(ii) Conclusion. In this Example 7, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network.

(4) Definitions. The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions, and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) Emergency services. The term emergency services means, with respect to an emergency medical condition –

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) Stabilize. The term to stabilize, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) Applicability date. The provisions of this section apply for plan years

(in the individual market, policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

10. Section 146.180 is amended as follows:

- A. Revising paragraph (a)(1).
- B. Adding a new paragraph (a)(2).
- C. Renumbering paragraphs (a)(2), (a)(3) and (a)(4) as (a)(3), (a)(4) and (a)(5), respectively.
- D. Replacing “2706” with “2727” each place it appears in paragraph (a)(1)(i)(F) and in Example 1 of paragraph (a)(3) (previously designated as (a)(2)).
- E. Making a conforming change to paragraph (a)(4)(i) (previously designated as (a)(3)(i)).
- F. Updating paragraph (c) to reflect the current address to which exemption elections may be mailed and providing a facsimile number to which elections may be faxed as an alternative to mailing elections.
- G. Removing the outdated parenthetical reference to § 146.125(a)(2) in paragraph (f)(2)(ii).
- H. Making a conforming change to paragraph (f)(3)(i).
- I. Adding a conforming sentence at the end of Example 1 in paragraph (h)(4)(i).
- J. Updating Example 4 in paragraph (i)(2)(iv).

The revisions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) Requirements subject to exemption—(1) Non-collectively bargained plans. (i) Plan years commencing before September 23, 2010. A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), for plan years commencing before September 23, 2010, from any or all of the following requirements:

(A) Limitations on preexisting condition exclusion periods described in § 146.111.

(B) Special enrollment periods for individuals and dependents described in § 146.117.

(C) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements in § 146.121(a)(1)(vi) and § 146.122 that prohibit discrimination with respect to genetic information.

(D) Standards relating to benefits for mothers and newborns described in § 146.130.

(E) Parity in the application of certain limits to mental health benefits described in § 146.136.

(F) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2727 of the PHS Act.

(G) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(ii) Plan years beginning on or after September 23, 2010. (i) A sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan for plan years beginning on or after September 23, 2010, only from any or all of the requirements described in paragraph (a)(1)(i)(D), (E), (F) or (G). With respect to those plan years, the notices required by paragraph (f) of this section must reflect the limitations set forth in this paragraph (a)(1)(ii).

(iii) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1)(i). The plan year commences September 1 each year. The plan is not subject to the limitations of paragraph (a)(1)(ii) until the plan year that commences on September 1, 2011. Accordingly, for that plan

year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(iv) Example 2. Same facts as in Example 1, except the plan year commences October 1 each year. The plan is subject to the limitations of paragraph (a)(1)(ii) beginning with the plan year that commences on October 1, 2010. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(2) Collectively bargained plans. (i) Special rule. Without regard to paragraph (b)(2) of this section, a group health plan that is governed by a collective bargaining agreement that was ratified before March 23, 2010, is subject to the limitations set forth in paragraph (a)(1)(ii) beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement. The notices required by paragraph (f) of this section, with respect to the first plan year subject to the limitations of paragraph (a)(1)(ii), must reflect those limitations.

(ii) Example. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1)(i) of this section. The collective bargaining agreement applies to five plan years, October 1, 2007 through September 30, 2012. For the plan year that commences on October 1, 2012, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1)(i)(A), (B) and (C). Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(3) Limitations. * * *

(A) Example 1. A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

* * *

(4) Stop-loss or excess risk coverage. For purposes of this section—(i) Subject to paragraph

(a)(4)(ii), * * *

(5) Construction. * * *

* * * * *

(c) Mailing address. The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Medicare Enrollment and Appeals Group, CPC, ATTN: HIPAA Opt-Out, 7500 Security Boulevard, C2-12-16, Baltimore, MD 21244-1850. Alternatively, the plan sponsor may fax the exemption election to 410-786-8001.

* * * * *

(f) * * *

(2) * * *

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, * * *

(3) * * *

(i) The specific requirements described in paragraphs (a)(1) or (a)(2) of this section, as applicable, from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

* * * * *

(h) * * *

(4) * * *

(i) Example 1. (A) * * *

(B) * * * However, regarding plan years that begin on or after September 23, 2010, the plan sponsor no longer can elect to exempt its plan from prohibitions against enrollment discrimination based on health status-related factors.

* * *

(i) * * *

(2) * * *

(iv) Example 4: A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from the requirements of paragraph (a)(1)(i)(E) of this section. The collective bargaining agreement applies to five plan years, 2007 through 2011. For the first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2007 through December 31, 2011. Prior to the dissemination of the annual notice for the 2010 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2007 through December 31, 2011. Accordingly, CMS would not invalidate the election for the 2010 plan year.

From: [Mayhew, James A. \(CMS/CPC\)](#)
To: [Corrigan, Dara \(HHS/OHR\)](#); [Kosin, Donald \(HHS/OGC\)](#)
Subject: RE: limited benefits v excepted benefits
Date: Wednesday, June 09, 2010 12:43:00 PM

I was walking down the hall just now to grab my lunch out of the refrigerator and a friend passing by said " I'm glad they let you out of your cage for a moment."

That summed it up nicely for me. People at CMS don't know me anymore since my door is always closed or I'm in DC.

I have this nagging fear about limited benefit plans- like the WH is going to come up with some idea to exempt them from annual limits that will not be sustainable. The whole purpose of health care reform (or I thought anyway) was to have these lousy plans go away so that individuals can get decent coverage. I know there will be a gap until 2014, but these plans are deceptive in the sense that people think they have more coverage than they actually have (which is very little).

From: Corrigan, Dara (HHS/ASPE)
Sent: Wednesday, June 09, 2010 12:22 PM
To: Kosin, Donald (HHS/OGC); Mayhew, James A. (CMS/CPC)
Subject: RE: limited benefits v excepted benefits

What is your view of the bracketed provision in the grandfather reg? Limited benefits plans?

The last call was not a great one from my perspective. It is very difficult when you are not part of the policy decisionmaking, when there are errors in the data, when you do not know what different parts of the Department think, etc. Basically DOL and Treasury were trying to take apart the bracketed portion of the grandfather rule and I was not in a position to defend the data or explain exactly what the Department's position is or whether we considered other alternatives. I also cannot project what behavioral changes are likely to occur in the individual market as a result of the bracketed section.

I end up feeling like an idiot or in a terrible position and not representing the Department well at all. I am tired of this process today I have to say.

Dara

From: Kosin, Donald (HHS/OGC)
Sent: Wednesday, June 09, 2010 9:31 AM
To: Mayhew, James A. (CMS/CPC); Corrigan, Dara (HHS/ASPE)
Subject: FW: limited benefits v excepted benefits

Jeanne's idea is below.

Notice: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use the information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

From: Choe, Ken (HHS/OGC)
Sent: Tuesday, June 08, 2010 9:27 PM
To: Kosin, Donald (HHS/OGC); Schulkin, Vicki (HHS/OGC); Fisher, Barbara (HHS/OGC); Hoffman, Janice (HHS/OGC)
Subject: FW: limited benefits v excepted benefits

i'm loathe to tell you of yet another twist/turn. based on my expression of discomfort with an enforcement theory, jeanne has proposed an entirely different approach -- one based on the definition of a restricted annual limit (which, for those of you who haven't read the politico article, is the new requirement of concern to the mini-med plans). as you can see below, i myself think that it holds promise (given, as jeanne says, that "restricted" annual limit is an wholly undefined term). if you can stomach continuing to follow this saga, i'd, of course, be interested in your thoughts.

From: Choe, Ken (HHS/OGC)
Sent: Tue 6/8/2010 9:26 PM
To: Brooks-LaSure, Chiquita (HHS/OHR); Lambrew, Jeanne (HHS/ASPE); Childress, Mark (HHS/OGC); Seshamani, Meena (HHS/ASPE)
Subject: RE: limited benefits v excepted benefits

yes, limits the policy to annual limits, and, as jeanne says, neatly disposes of the 2014 issue. (bonus: no need to amend the grandfather regulation. again.)

as for whether the policy would sweep in other plans, i note that, if memory serves, in addition to the limiting principle of premium spikes, the statute sets forth another limiting principle: "access to needed services." perhaps there's something singular about limited benefits plans both with respect to premium spike and with respect to coverage access (e.g., the types of populations to which they tend to be relevant) that would make them especially promising candidates for waivers? also, i note that, on a somewhat lesser note, the question of whether the policy would sweep in other plans is also present under an enforcement discretion theory. there, the question is whether a justification based on the notion that pre-2014 enforcement would lead to loss of coverage could also apply to other plans, i.e., whether there's a non-arbitrary distinction for treating limited benefits plans differently (which there might be).

From: Brooks-LaSure, Chiquita (HHS/OHR)
Sent: Tue 6/8/2010 8:53 PM
To: Lambrew, Jeanne (HHS/ASPE); Choe, Ken (HHS/OGC); Childress, Mark (HHS/OGC); Seshamani, Meena (HHS/ASPE)
Subject: RE: limited benefits v excepted benefits

i like, because it limits the exemption to the annual rule, rather than exempting them from everything (like MLRs, rescissions). however, do you think this new waiver would sweep up alot of regular plans as well? that might not be bad if we want to mitigate premium increases but will of course mean fewer people benefit from the policy.

-----Original Message-----

From: Lambrew, Jeanne (HHS/ASPE)

Sent: Tue 6/8/2010 8:38 PM

To: Choe, Ken (HHS/OGC); Childress, Mark (HHS/OGC); Brooks-LaSure, Chiquita (HHS/OHR); Seshamani, Meena (HHS/ASPE)

Subject: RE: limited benefits v excepted benefits

One other thought, since I am equally queszy about a broad rule. What if we leave grandfather as is and, instead, create an exceptions or waiver processin in the patients protection rule.

It could be something like, if a plan subjected to the restricted annual limits policy has evidence that the change from in its annual limit in place on March 23 would result in significant premium increase that would disrupt coverage, then it can apply for a delayed effective date.

This shoudl be legal given that we have to define the damn term "restricted" anyway, and are supposed to take into account premiums.

Given that there are so many crappy plans out there, I'd rather make it an exception than a rule: if that Cigna plan has real evidence, they can come and prove it. This will link exempting plans from the annual limits policy with the reason we care about: premium spikes.

If we delay the effective date, then we are giving them time to figure out a new business model, although obviously each year as the limit goes up, the premium effect will be greater making it easier to prove the spike. We could replace delayed effective date with a transitional limit, although I hate the idea of making up another set fo dollar amounts.

Lastly, we don't have to worry about 2014 since our "restricted" authority goes away.

Thoughts?

From: [Baum, Beth - EBSA](#)
To: [Baum, Beth - EBSA](#); [Benson, Susanna - SOL](#); [Butikofer, James - EBSA](#); [Corrigan, Dara \(HHS/OHR\)](#); [Cosby, Chris - EBSA](#); [Helen.Morrison@do.treas.gov](#); [Karen Levin - HOME](#); [Knopf Kevin - OTP](#); [Kosin, Donald \(HHS/OGC\)](#); [Levin Karen](#); [Mayhew, James A. \(CMS/CPC\)](#); [Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV](#); [Schumacher, Elizabeth - EBSA](#); [Tawshunsky Alan](#); [Taylor, William - SOL](#); [Turner, Amy - EBSA](#)
Subject: RE: Pkg of 6 Reg Text 6.8.10 5pm
Date: Tuesday, June 08, 2010 4:51:37 PM
Attachments: [Pkg of 6 Joint Preamble 6.8.10 9am.doc](#)

Here is the preamble as of now...

-----Original Message-----

From: Baum, Beth - EBSA
Sent: Tuesday, June 08, 2010 4:51 PM
To: Baum, Beth - EBSA; Benson, Susanna - SOL; Butikofer, James - EBSA; 'Corrigan, Dara (HHS/ASPE)'; Cosby, Chris - EBSA; Helen.Morrison@do.treas.gov; Karen Levin - HOME; 'Knopf Kevin - OTP'; 'Kosin, Donald (HHS/OGC)'; 'Levin Karen'; 'Mayhew, James A. (CMS/CPC)'; 'Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV'; Schumacher, Elizabeth - EBSA; Tawshunsky Alan; Taylor, William - SOL; Turner, Amy - EBSA
Subject: Pkg of 6 Reg Text 6.8.10 5pm

Here is the updated version of the six-pack: we'll go over the preamble at 930am in the morning tomorrow.

[Billing Codes: 4830-01-P; 4510-29-P; 4120-01-P]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 54 and 602

TD

RIN 1545-XXXX

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-XXXX

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

OCIIO-XXXX-IFC

45 CFR Part 147

RIN XXXX-XXXX

Interim Final Rules for Group Health Plans and Health Insurance Issuers under the Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, discrimination in favor of highly compensated individuals, patient protections, and non-federal governmental plans.

DATES: Effective date. These interim final regulations are effective on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Comment date. Comments are due on or before **[INSERT DATE 90 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Applicability date. These interim final regulations generally apply to group health plans and group health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**. These interim final regulations generally apply to individual health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB42, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Email: [E-OHPSCA\[XXXX\].EBSA@dol.gov](mailto:E-OHPSCA[XXXX].EBSA@dol.gov).

- Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: RIN 1210-AB42.

Comments received by the Department of Labor will be posted without change to www.regulations.gov and www.dol.gov/ebsa, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIO-9991-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.
2. By regular mail. You may mail written comments to the following address ONLY:
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services,
Attention: OCIO-9991-IFC,
P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Office of Consumer Information and Insurance Oversight,
Department of Health and Human Services,
Attention: OCIIO-9991-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Office of Consumer Information and Insurance Oversight,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A

stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard,

Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-118412-10, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: CC:PA:LPD:PR (REG-118412-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-118412-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786-1565.

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's website (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website

(http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp) and information on health reform can be found at <http://www.healthreform.gov>..

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of part A of title XXVII of the PHS Act applicable under ERISA and the Code to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if those provisions of the PHS Act were included in ERISA and the Code. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The

¹ The term “group health plan” is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term “health plan”, as used in other provisions of title I of the Affordable Care Act. The term “health plan” does not include self-insured group health plans.

preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of the Affordable Care Act are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers stricter requirements than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations implementing the revised PHS Act sections 2701 through 2719A in several phases. The first publication in this series was a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). The second publication was interim final regulations implementing PHS Act section 2714 (requiring dependent coverage of children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third publication was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on May XX, 2010 (75 FR XXXXX). These interim final regulations are being published to implement PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding rescissions), 2716 (prohibiting discrimination in favor of highly compensated individuals), 2719A (regarding patient protections), and 2722 (regarding the application of the Affordable Care Act provisions to nonfederal governmental plans). PHS

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

Act section 2704 generally is effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014. However, with respect to enrollees, including applicants for enrollment, who are under 19 years of age, PHS Act section 2704 is effective for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.³ The rest of these provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

II. Overview of the Regulations:

A. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815-2704, 29 CFR 2590.715-2704, 45 CFR 147.108)

Section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA⁴ rules relating to preexisting condition exclusions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under certain circumstances. The Affordable Care Act provision prohibits any preexisting condition exclusions imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan

³ Section 1255 of the Affordable Care Act. See also section 10103(e)-(f) of the Affordable Care Act.

⁴ HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

years (in the individual market, policy years) beginning on or after September 23, 2010.

HIPAA generally defines a preexisting condition exclusion⁵ as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

For group health plans and group health insurance issuers, a denial of coverage of an individual based on a preexisting condition exclusion also violates the HIPAA rules prohibiting discrimination based on a health factor. Beginning on January 1, 2014, a denial of coverage of an individual based on a preexisting condition would also violate more than one provision in the individual market: the prohibition against preexisting condition exclusions, the guaranteed availability requirement, and the prohibition against discrimination based on health status. Of course, if an individual was denied coverage beginning in 2014 on a ground other than the existence of a preexisting condition or a health factor, the denial would only violate the right to guaranteed availability.

The protections in the new PHS Act section 2704 generally apply to plan years (in the individual market, policy years) beginning on or after January 1, 2014. The Affordable Care Act provides, however, that these protections apply with respect to enrollees under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. An enrollee under age 19 thus could not be denied benefits based on a preexisting condition. In

⁵ Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1); after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1). See also ERISA section 701(b)(1) and Code section 9801(b)(1).

order for an individual to receive the same protection that applies in the case of such an enrollee, the individual similarly could not be denied benefits (in whole or part) based on a preexisting condition. Thus, for plan years (in the individual market, for policy years) beginning on or after September 23, 2010, PHS Act section 2704 protects individuals under age 19 with a preexisting condition from being denied coverage under a plan (in whole or part) based on the preexisting condition.

These interim final regulations do not change the HIPAA rule that a plan's or issuer's exclusion of benefits for a condition from the plan or policy regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. This point is still relevant for these interim final regulations and is illustrated with examples in the HIPAA regulations on preexisting condition exclusions.⁶ (Other requirements of Federal or State law, however, may prohibit certain benefit exclusions.)

The interim final regulations under PHS Act section 2714 (relating to the continuation of dependent coverage until age 26)(75 FR 27122, May 13, 2010) provide that the terms of a plan or policy for dependent coverage cannot vary based on the age of a child, except for children age 26 or older. These interim final regulations amend those regulations to clarify that, for plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or policy may impose a preexisting condition exclusion (consistent with the rules of 26 CFR 54.9801-3, 29 CFR 2590.701-3, and 45 CFR 146.111) on children who are age 19 or older even though this is prohibited with respect to children under age 19.

Application to grandfathered health plans. Under the statute and these interim final regulations, a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a

⁶ See Examples 6, 7, and 8 in 26 CFR 54.9801-3(a)(1)(ii), 29 CFR 701-3(a)(1)(ii), 45 CFR 146.111(a)(1)(ii).

grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704. See 26 CFR 54.9815-1251, 29 CFR 2590.715-1251, and 45 CFR 147.140 regarding status as a grandfathered health plan.

B. PHS Act Section 2711, Lifetime and Annual Limits (26 CFR 54.9815-2711, 29 CFR 2590.715-2711, 45 CFR 147.???)

Section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits. However, these interim final regulations provide that the annual limit rules do not apply to health flexible spending arrangements.⁷

The statute also allows “restricted annual limits” with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. In addition, the statute provides that, with respect to benefits that are not essential health benefits, a plan or issuer may impose annual or lifetime per individual limits on specific covered benefits. Rather than provide a definition of “essential health benefits,” these interim final regulations cross-reference section 1302(b) of the Affordable Care Act and applicable regulations.⁸

These interim final regulations clarify that the prohibition under PHS Act section 2711 does not prevent a plan or issuer from excluding all benefits for a condition, but if any benefits are provided for a condition, then the requirements of the rule apply. Therefore, an exclusion of all benefits for a condition is not considered to be an annual or lifetime dollar limit.

⁷ Section 9005 of the Affordable Care Act specifically limits the annual amount of salary reduction contributions for health flexible spending arrangements.

⁸ Regulations under section 1302(b) of the Affordable Care Act have not yet been issued.

The statute and these interim final regulations provide that for plan years (in the individual market, policy years) beginning before January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may only establish a restricted annual limit on the dollar value of essential health benefits. The statute provides that in defining the term “restricted annual limit,” the Departments “ensure that access to needed services is made available with a minimal impact on premiums.”

In establishing the restricted annual limit, the Departments considered several factors: (1) the current use of annual limits in the group and individual market; (2) the average premium impact of imposing different annual limits on the individual, small group, and large group markets; (3) the number of individuals who will continue to have annual medical expenses that exceed an annual limit; and (4) the possibility that a plan or issuer would switch to an annual limit when lifetime limits are prohibited.

Approximately four percent of large employer plans, eight percent of small employer PPO plans, and 19 percent of individual market plans currently have annual limits. Although available data show that very few health insurance plans impose annual limits, at least half of small group plans and over 75 percent of policies in the individual market impose lifetime limits. The 2009 Kaiser Family Foundation/HRET Survey of Employers found that less than one percent of covered workers had lifetime limits less than \$1 million, 16 percent had limits between \$1 million and \$1.99 million, 43 percent had lifetime limits of \$2 million or more, and 41 percent had no lifetime maximum.⁹ Of those enrollees in indemnity plans with lifetime limits, 63 percent of single enrollees and 44 percent of family enrollees had lifetime maximums less than \$2 million while less than one percent of enrollees in network-based arrangements,

⁹ See the Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), at <http://ehbs.kff.org/pdf/2009/7936.pdf>.

such as HMOs, PPOs, or high deductible health plans with savings options had lifetime maximums less than \$2 million. While it is possible that those plans with lifetime limits will switch to annual limits prior to the elimination of annual limits in 2014, group health plans and health insurance issuers could use a number of changes to benefit design to mitigate any potential premium increases.

In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, these interim final regulations adopt a three-year phased approach for restricted annual limits. This phased-in approach provides ample opportunity for plans with relatively low annual limits (e.g., \$100,000, \$250,000, or \$500,000) to more gradually make adjustments that might smooth any increase in costs that might result from the increased minimum annual limits under these interim final regulations. The proposed annual limit levels ensure that the vast majority of individuals who may experience high medical costs during the year will continue to have access to coverage.

These interim final regulations provide the following minimum amounts for annual limits on the dollar value of benefits that are essential health benefits for plan years (in the individual market, policy years) beginning before January 1, 2014:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, \$750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, \$1.25 million; and
- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2 million.

Comment [b1]: Can we get rid of this whole paragraph? Cross reference the discussion in the economic analysis that goes over these same statistics?

If not, use cite for the 1st sentence from economic analysis cite to Mercer survey (FN 31 in old draft)

As these are minimums for plan years (in the individual market, policy years) beginning before 2014, plans or issuers may always use higher annual limits or impose no limits. Plans and policies with plan or policy years that begin between September 23 and December 31 have more than one plan or policy year under which the \$2 million minimum annual limit is available; however, a plan or policy generally may not impose an annual limit for a plan year beginning after December 31, 2013.

The minimum annual limits for plan or policy years beginning before 2014 apply on an individual-by-individual basis. Thus, any overall annual dollar limit on benefits applied to families may not operate to deny a covered individual the minimum annual benefits for the plan year (in the individual market, policy year). These interim final regulations clarify that, in applying annual limits for plan years (in the individual market, policy years) beginning before January 1, 2014, the plan (or policy) may only take into account essential health benefits.

These interim final regulations provide an enrollment (in the individual market, reinstatement) opportunity for individuals who reached their lifetime limits in a group health plan or health insurance coverage and remain otherwise eligible for the coverage. In the individual market, this reinstatement opportunity does not apply to individuals who reached their lifetime limits in individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in a family policy in the individual market while other family members remain in the coverage. This opportunity must be made available no later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. See discussion of transitional rules in Section II.G. of this preamble.

Application to grandfathered health plans. The statute and these interim final regulations relating to the prohibition on lifetime limits apply to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the prohibition on annual limits, including the special rules regarding restricted annual limits for plan years beginning before January 1, 2014, apply to group health plans and group health insurance coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage.

C. PHS Act Section 2716, Prohibiting Discrimination in Favor of Highly Compensated Individuals (26 CFR 54.9815-2716, 29 CFR 2590.715-2716, 45 CFR 147.2716)

PHS Act section 2716 and these interim final regulations incorporate the nondiscrimination rules of section 105(h) of the Code and apply them to group health plans that are not self-insured plans. Section 105(h) generally prohibits self-insured medical reimbursement plans from discriminating in favor of highly compensated individuals in eligibility classifications or in benefits. Section 105(b) of the Code generally excludes from an employee's income (otherwise subject to federal income taxation) amounts received as reimbursement of medical care expenses for the employee or the employee's spouse, dependents, or children who have not attained age 27 by the end of the taxable year. If a self-insured medical reimbursement plan does not comply with the requirements of section 105(h), the general exclusion from income (and hence, from federal income taxation) under section 105(b) does not apply with respect to highly compensated individuals. Highly compensated individuals are defined in section 105(h).

PHS Act section 2716 and these interim final regulations incorporate the substantive nondiscrimination requirements of Code section 105(h) but not the tax sanctions. An insured group health plan failing to comply with the nondiscrimination requirements of Code section 105(h) is subject to the sanctions and remedies that generally apply for a plan failing to comply with the requirements of chapter 100 of the Code (generally, an excise tax of \$100 per day per individual for each day the plan does not comply with the requirement), part 7 of ERISA (a civil action to enjoin a noncompliant act or practice or for appropriate equitable relief), or Title XXVII of the PHS Act (civil money penalties of \$100 per day per individual for each day the plan does not comply with the requirement). Thus, if a self-insured plan fails to comply with Code section 105(h), highly compensated individuals lose a tax benefit; if an insured group health plan fails to comply with Code section 105(h), the plan is subject to a civil action to compel it to provide nondiscriminatory benefits and the plan or plan sponsor is subject to an excise tax or civil money penalty of \$100 per day per individual. Rather than restate the rules under section 105(h) of the Code, these interim final regulations incorporate by reference those rules and applicable regulations.

Application to grandfathered health plans. The rules prohibiting discrimination in favor of highly compensated individuals do not apply to grandfathered health plans (but the rules of Code section 105(h) continue to apply to self-insured plans).

D. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815-2716, 29 CFR 2590.715-2716, 45 CFR 147.XXX)

Section 2719A(a) of the PHS Act and these interim final regulations provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant,

beneficiary, and enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In accordance with section 2590.715(e) of these interim final regulations, the plan or issuer must provide a notice informing each participant (or in the individual market, the primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

The statute and these interim final regulations impose a requirement for the designation of a pediatrician similar to the requirement for the designation of a primary care physician. Specifically, if a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the notice requirements of paragraph (e) of these interim final regulations. The plan's general terms regarding pediatric care otherwise are unaffected, including any exclusions with respect to coverage of pediatric care.

The statute and these interim final regulations provide rules for a group health plan, or a health insurance issuer offering group or individual health insurance coverage, that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. In such a case, the plan or issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology. Nothing in these interim

final regulations precludes the plan or issuer from requiring in-network obstetrical or gynecological provider to otherwise adhere to policies and procedures regarding referrals, prior authorization for treatments, and the provision of services pursuant to a treatment plan approved by the plan or issuer. The plan or issuer must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

The general terms of the plan or coverage regarding exclusions of coverage with respect to obstetrical or gynecological care are otherwise unaffected. These interim final regulations do not preclude the plan or issuer from requiring that the obstetrical or gynecological provider notify the primary care provider or the plan or issuer of treatment decisions.

Application to grandfathered health plans. The statute and these interim final regulations relating to certain patient protections do not apply to grandfathered health plans. However, other Federal or State laws related to these patient protections may apply regardless of grandfather status.

E. Individual Market and Non-Federal Governmental Plan Reforms

1. References to the Public Health Service Act

Conforming changes are made throughout Parts 144 and 146 to reflect changes made by the Patient Protection and Affordable Care Act (Affordable Care Act), which renumbered certain sections of title XXVII of the Public Health Service Act (PHS Act).

2. Definitions (45 CFR 144.103)

The definition of “policy year” is added and it is defined as the 12-month period that is designated in the policy documents of individual health insurance coverage. If the policy document does not designate a policy year (or no such document exists), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year. The Affordable Care Act uses the term “plan year” in referring to the period of coverage in both the individual and group health insurance markets. The term “plan year,” however, is generally recognized as having only relevance in the group health insurance market. Accordingly, these interim final regulations substitute the term “policy year” for “plan year” in defining the period of coverage in the individual health insurance market.

These interim final regulations revise the definition of “preexisting condition exclusion” to clarify that the denial of an application for coverage because of a preexisting condition in the individual health insurance market is a preexisting condition exclusion. This definition at 45 CFR 144.103 is cross-referenced in both 45 CFR 146.111(a)(1) and 45 CFR 147.2704, and it applies in both the group and individual health insurance markets, and also to entities that provide coverage to Federally eligible individuals pursuant to 45 CFR Part 148.

3. Treatment of Non-Federal Governmental Plans (45 CFR 146.180)

As noted, the Affordable Care Act made numerous changes to Title XXVII of the PHS Act, including to former section 2721(b)(2), which permitted the sponsor of a self-funded non-Federal governmental plan, as defined in 45 CFR 144.103, to elect to exempt the plan from certain requirements of Title XXVII of the PHS Act.¹⁰ Section 1001(4) of the Affordable Care Act re-designated section 2721 as section 2735. Affordable Care Act section 1562(a)(2)

¹⁰ This is referred to here as the “opt-out provision.”

amended section 2735 by adding a new subparagraph (a)(2)(E), which prohibits a sponsor of a self-funded non-Federal governmental plan from electing to exempt the plan from Subparts I and II in Part A of the revised Title XXVII. Affordable Care Act section 1562(c)(12) then amended section 2735, including re-designating subsection (b)(2) as subsection (a)(2), and then by redesignating section 2735 as section 2722.

Subpart I (“General Reform”) contains the substance of the provisions of the original Subpart 1 of Part A of title XXVII of the PHS Act, including limitations on preexisting condition exclusion periods, requirements for special enrollment, and prohibitions against discriminating against individual participants and beneficiaries based on health status or genetic information. Therefore, as a result of section 2722(a)(2)(E), self-funded non-Federal governmental plans cannot opt out of (elect to be exempted from) the foregoing provisions, which are now in Subpart I, starting with plan years beginning on or after September 23, 2010.

However, while section 2722(a)(2)(E) precludes an opt-out election with respect to the new subparts I and II of Part A, an opt-out election is still permitted with respect to the provisions in Subpart 2 of Part A. Affordable Care Act section 1001(2) re-designated sections 2704 through 2707 (which formerly set forth the provisions relating to the Newborns’ and Mothers’ Health Protection Act of 1996, the Mental Health Parity Act of 1996 (as amended by the Mental Health Parity and Addiction Equity Act of 2008), the Women’s Health and Cancer Rights Act of 1998, and Michelle’s Law (2008)) as new sections 2725 through 2728, respectively, which are contained in a revised Subpart 2, “Exclusion of Plans; Enforcement; Preemption.”¹¹ A sponsor of a self-funded non-Federal governmental plan may continue to elect

¹¹ The Affordable Care Act created Subparts I and II of Part A, but did not remove Subpart 2. Therefore, Subpart II (Roman numeral) and Subpart 2 (Arabic numeral) are separate, coexisting subparts.

to exempt its plan from the requirements of Subpart 2 (which is separate from Subpart II) of Part A of Title XXVII since the prohibition in section 2722(a)(2)(E) does not reference Subpart 2.

Affordable Care Act section 1004(a) provides that the amendments made by section 1001 are “effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act[.]” The Affordable Care Act was enacted on March 23, 2010. Therefore, the amendments made by section 1001, as further amended by subsections (a) and (c)(12) of section 1562, are effective for plan years beginning on or after September 23, 2010.

The Affordable Care Act makes no exception for plan years that are governed by a previously ratified collective bargaining agreement under which the plan sponsor has elected to exempt the self-funded non-Federal governmental plan from one or more requirements of Subpart 1 (as it was designated prior to enactment of the Affordable Care Act). Section 1251 of the Affordable Care Act has special rules for "grandfathered" plans, including an exception in subsection (d) for collectively bargained plans. However, the exception only applies for "**health insurance coverage** maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this Act." (Emphasis added.) New section 2722(a)(2)(B)(ii) of the PHS Act, however, indicates that an opt-out election made by a group health plan maintained pursuant to a collective bargaining agreement remains in effect “for the term of such agreement.” Since this provision was not amended by the Affordable Care Act, we view that it takes precedence over the provisions of section 1251(d). Accordingly, the interim final regulations state that a group health plan that is maintained pursuant to a collective bargaining agreement that was ratified before March 23, 2010 and that has been exempted from any provision in the former Subpart 1 will not have to come into compliance with those provisions until beginning with the

commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement.

Non-federal governmental plans not maintained pursuant to a collective bargaining agreement will not be permitted to elect to opt-out of the provisions in the former Subpart 1 for plan years beginning on or after September 23, 2010. Although section 1251(b) of the Affordable Care Act provides grandfathering protection for plans that existed before March 23, 2010, opt-out elections initially submitted or renewed on or after the amendment effective date of March 23, 2010 for any provision in the former Subpart 1 are not subject to that protection.

In addition to revisions that reflect changes made by the Affordable Care Act, section 146.180 is further revised to make certain changes that are unrelated to the Affordable Care Act, such as adding the requirements of Michelle's law to the list of title XXVII requirements set forth at section 146.180(a)(1) from which self-funded non-Federal governmental plans may be exempted, updating the address to which an opt-out election should be submitted, updating an example to reflect more recent dates, and removing outdated text.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good

cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, numerous provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Grandfathered health plans are exempt from many of these provisions while group health plans and group and individual health insurance coverage that are not grandfathered health plans must comply with them. The determination of whether a plan or health insurance coverage is a grandfathered health plan therefore could substantially affect the design of the plan or health insurance coverage.

The six-month period between the enactment of the Affordable Care Act and the applicability of many of the provisions affected by grandfather status would not allow sufficient time for the Departments to draft and publish proposed regulations, receive and consider comments, and draft and publish final regulations. Moreover, regulations are needed well in advance of the effective date of the requirements of the Affordable Care Act. Many group health plans and health insurance coverage that are not grandfathered health plans must make significant changes in their provisions to comply with the requirements of the Affordable Care Act. Moreover, plans and issuers considering other modifications to their terms need to know whether those modifications will affect their status as grandfathered health plans. Accordingly, in

order to allow plans and health insurance coverage to be designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact and Paperwork Burden

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a,

1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

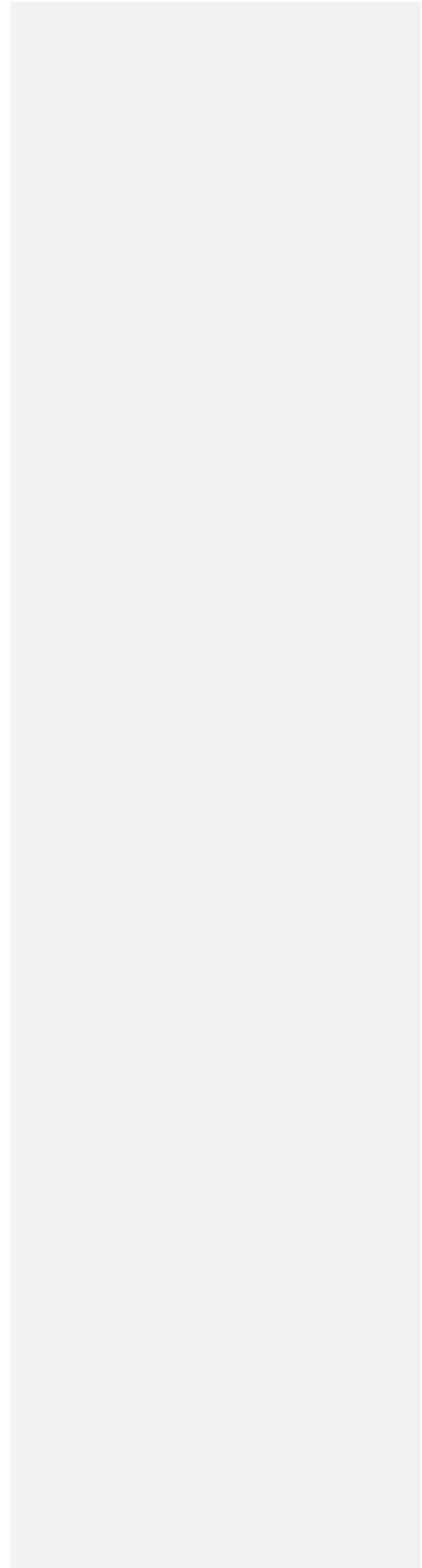
Steven T. Miller
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved:

Michael F. Mundaca
Assistant Secretary of the Treasury (Tax Policy).

Signed this _____ day of _____, 2010.

Phyllis C. Borzi
Assistant Secretary
Employee Benefits Security Administration
Department of Labor



Approved: _____

Jay Angoff,

Director,

Office of Consumer Information and Insurance
Oversight.

Approved: _____

Kathleen Sebelius,

Secretary, Department of Health and Human
Services.

From: [Baum, Beth - EBSA](#)
To: [Baum, Beth - EBSA](#); [Benson, Susanna - SOL](#); [Butikofer, James - EBSA](#); [Corrigan, Dara \(HHS/OHR\)](#); [Cosby, Chris - EBSA](#); [Helen.Morrison@do.treas.gov](#); [Karen Levin - HOME](#); [Knopf Kevin - OTP](#); [Kosin, Donald \(HHS/OGC\)](#); [Levin Karen](#); [Mayhew, James A. \(CMS/CPC\)](#); [Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV](#); [Schumacher, Elizabeth - EBSA](#); [Tawshunsky Alan](#); [Taylor, William - SOL](#); [Turner, Amy - EBSA](#)
Subject: Pkg of 6 Reg Text 6.8.10 5pm
Date: Tuesday, June 08, 2010 4:50:50 PM
Attachments: [Pkg of 6 Reg Text 6.8.10 5pm.doc](#)

<<Pkg of 6 Reg Text 6.8.10 5pm.doc>> Here is the updated version of the six-pack: we'll go over the preamble at 930am in the morning tomorrow.

From: [Corrigan, Dara \(HHS/OHR\)](#)
To: [Lambrew, Jeanne \(HHS/OS/OHR\)](#); [Childress, Mark \(HHS/OGC\)](#); [Kronick, Richard \(HHS/ASPE/HP\)](#); [Angoff, Jay \(HHS/OCIIO\)](#); [Brooks-LaSure, Chiquita \(HHS/OHR\)](#); ["Duggan, Mark G."](#); ["Helen.Morrison@do.treas.gov"](#); ["Mark.Iwry@do.treas.gov"](#); ["Borzi.Phyllis@dol.gov"](#); ["maguire.daniel@dol.gov"](#); ["Piacentini.joseph@dol.gov"](#); [Seshamani, Meena \(HHS/OHR\)](#); [Choe, Ken \(HHS/OGC\)](#); [Kosin, Donald \(HHS/OGC\)](#); ["Turner, Amy - EBSA"](#); ["Baum, Beth - EBSA"](#); ["Knopf Kevin - OTP"](#); [Mayhew, James A. \(CMS/CPC\)](#); ["Levin Karen"](#); ["Schumacher, Elizabeth - EBSA"](#)
Subject: I have attempted to do a quick summary of the
Date: Monday, June 07, 2010 1:04:28 PM
Attachments: [Restricted annual limits options.doc](#)

two options presented at the Deputies Meeting today with some examples to illustrate option 1. With the caveat that these are my thoughts after one hour, I think this should at least get the conversation started so that we can finalize a decision. Please circulate to anyone that I may have inadvertently left off the list.

Happy to answer questions.

Dara A. Corrigan
Director of Policy Analysis
Office of Health Reform
(202) 401-8401

Option 1: Modification to the Grandfather Rule

Summary of the Rule: As currently structured, the grandfather regulation lists those changes that would cause cessation of grandfather status. The proposal would be to add a provision that would reference section 2711 and the elimination of lifetime limits. The new provision in the grandfather regulation would state that if a group health plan, with a lifetime limit and no annual limits, replaced the lifetime limit with an annual limit that was less than the dollar amount of the lifetime limit, it would cease to be a grandfathered plan. For group plans with both lifetime and annual limits, the group plan would cease to be a grandfathered plan if it lowered its annual limit. For group plans with annual limits only, the plan would lose grandfather status if it lowered the annual limit. This rule assumes that the current definition of restricted annual limits in the omnibus regulation remains the same, with a three tier gradual increase (750,000 for 2011, 1.25 million for 2012, and 2 million for 2013)

Examples:

1. Group health plan in existence on March 23, 2010 has a lifetime limit of \$1 million. Plan can replace the \$1 million lifetime limit with an annual limit of \$1 million.
 - a. In 2011, if the plan lowers the annual limit to \$750,000, it would cease to be a grandfathered plan.
 - b. In 2012, the group health plan would have a legal obligation to raise the annual limit to \$1.25 million.
2. Group health plan in existence on March 23, 2010 has a lifetime limit of \$500,000 and an annual limit of \$200,000. Group health plan must raise annual limit to \$750,000 for plan year beginning on or after September 13, 2010 but before September 23, 2011.
3. Group health plan in existence on March 23, 2010 has an annual limit of \$50,000. Group health plan must raise annual limit to \$750,000 for plan year beginning on or after September 13, 2010 but before September 23, 2011.

Potential Issues:

1. The restricted annual limits only apply to essential benefits. A plan or policy can have low annual limits for non-essential benefits. To the extent that a grandfathered group health plan has lifetime and/or annual limits that include essential and non-essential benefits, we will need to figure out how to reconcile.

Option 2: Modification to the Restricted Annual Limits Provision

Summary of the Rule: We would keep the same three tier structure described above, but we would modify the definition of restricted annual limits. Under the new definition, all group health plans and health insurance issuers may establish the three tier structure for annual limits with the following exceptions:

- grandfathered group plans that eliminate lifetime limits cannot replace the lifetime limits with annual limits
- grandfathered group plans with annual limits higher than the three tier structure cannot lower their annual limits

From: [Seshamani, Meena \(HHS/OHR\)](#)
To: [Kosin, Donald \(HHS/OGC\)](#); [Corrigan, Dara \(HHS/OHR\)](#); [Mayhew, James A. \(CMS/CPC\)](#)
Cc: [Larsen, Steven \(HHS/OCIIO\)](#)
Subject: annual limits
Date: Sunday, June 06, 2010 7:09:36 PM
Attachments: [20100604 Defining Restricted Annual Limits iml.doc](#)

Hi all, I am relaying a clarification for the annual limits policy that Mark Childress is presenting tomorrow. Paper attached.

As you may know, the question is whether we could be “nicer” with our policy. This would entail a “hold harmless” meaning that if a grandfathered plan had an annual limit that was more generous than the \$750K etc tiers, it could not become more restrictive by moving to the \$750K, \$1.25m, \$2m levels. This also means that a plan that had a lifetime limit but no annual limit couldn’t impose an annual limit.

For a brand new plan, there is no baseline annual limit, so they could go to the \$750K etc tiers.

The question arises with a non-grandfathered plan, which did have a baseline annual limit, but is now kind of like a new plan. How would they get treated? How could they get treated? I think ideally they would still be viewed as an existing plan that had a baseline annual limit so it couldn’t become less generous and move to \$750K, (thereby keeping the spirit of Mark’s “hold harmless” theme) but wanted to ask the experts what is actually possible with all of this.

Thanks.
Meena

Meena Seshamani, MD, PhD
Deputy Director
Office of Health Reform
Dept of Health and Human Services
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Change in Option on Defining Restricted Annual Limits

Section 1001 of the Patient Protection and Affordable Care Act (the Act) and Section 2711 of the Public Health Service Act (PHS) provide that a group health plan and health insurance issuers offering group or individual health insurance prior to 2014 must eliminate lifetime limits, but may impose a restricted annual limit on essential health benefits. The Secretary must define a restricted annual limit that ensures that access to needed services is available with a minimal impact on premiums.

Current State of the Market

Currently, 63 percent of large employer plans, 52 percent of small employer plans and 89 percent of individual market plans have lifetime limits. Approximately 4 percent of large employer plans, 8 percent of small employer PPO plans and 19 percent of individual market plans currently have annual limits, though very limited data exists here.

Policy Considerations

After our last WH Deputies meeting on this topic, a policy was determined that would:

1. Eliminate lifetime limits
2. Impose graded annual limits of \$750,000 in 2011, \$1.25 million in 2012, and \$2 million in 2013 (and then no annual limit in 2014)
3. Allow plans that do not have an annual limit or have an annual limit higher than the restricted level to come to that level. This is pertinent for plans that had a lifetime limit but no annual limit, to allow them to change over to potentially mitigate premium increases.

HHS is concerned that #3 could be perceived as worsening consumer protections for people who previously did not have an annual limit, or had a less restrictive one. We recommend for the group to consider that we do not allow plans with annual limits currently above the restricted amount (ie, either a higher dollar value or no annual limit) to come to the restricted annual limit amount.

It is believed that such an approach would have a minimal impact on premiums, as presented below, while providing considerable consumer protections.

As only a small percent of plans currently have annual limits and very limited data exists on annual limits, the estimates below should be carefully considered and evaluated. These estimates also assume that no other compensatory changes would be made to mitigate premium increases, and therefore represent the high end of the range given the available data.

Estimates

(Please note that limited data exists on annual limits. However, for lifetime limits, there is sufficient data both in terms of prevalence of lifetime limits in the insurance markets, and in terms of incidence of people passing lifetime limit thresholds in terms of their spending.)

1. Elimination of Lifetime Limits

- If we assume that plans or policies with lifetime limits will not impose new restricted annual limits, the impact on premiums overall is estimated to be under 1 percent for both individual and small group markets.

Table 1: Large Group Effects

Current Limit	Prevalence among Plans	% Premium Change by Eliminating Limit
Unlimited	37%	0.00%
Under 1,000,000	1%	0.02%
1,000,000-1,999,999	18%	0.20%
2,000,000 +	45%	0.22%
Average across market		0.14%

Table 2: Small Group Effects

Current Limit	Prevalence among Plans	% Premium Change by Eliminating Limit
Unlimited	48%	0.00%
Under 1,000,000	1%	0.02%
1,000,000-1,999,999	12%	0.13%
2,000,000 +	39%	0.19%
Average across market		0.09%

Table 3: Individual Market Effects

Current Limit	Prevalence among Plans	% Premium Change by Eliminating Limit
Unlimited	11%	0.00%
Under 1,000,000	2%	0.03%
1,000,000-1,999,999	1%	0.01%
2,000,000 +	86%	0.43%
Average across market		0.37%

Data Sources: KFF/HRET Employer Health Benefits Survey; AHIP Individual Market Survey; Medical Expenditure Panel Survey-Household Component calibrated to National Health Account levels for 2010 with additional data on high-cost claims from the Society of Actuaries.

- As a separate external estimate, PricewaterhouseCoopers calculated that increasing lifetime limits from \$1 million to \$5 million would increase average premiums by \$3 per month for single coverage and \$8 for family coverage.

2. Imposing Restricted Annual Limits

The results below summarize the premium analyses that led to the staged approach to restricted annual limits.

- Table 1 summarizes available data on the prevalence of different annual limits in the various insurance markets.
- Table 2 describes the premium impact for a particular plan moving from baseline annual limits to the new restricted annual limit. For example, if a plan with an annual limit of \$250K increased the annual limit to \$500k, the estimated premium impact would be 3.7%. These impacts are specific to the plans affected by the provision (those currently with annual limits).
- Table 3 looks at the estimated number/percentage of people whose medical expenditures exceed the various thresholds noted above.
- Table 4 provides the cumulative impact of moving to higher annual limits, phased over 3 years. This incorporates the prevalence of the various annual limits in the different markets.

Table 1: Prevalence of Annual Limits by Market

	Large	Small	Individual
Under 250,000	0.01%	0.43%	0.39%
250k - 499,999	0.04%	1.29%	1.17%
500k - 999,999	0.06%	1.71%	1.56%
1 mil - 1,999,999	2.28%	5.47%	12.00%
2,000,000 +	5.77%	5.47%	3.84%
Total	8.17%	14.36%	18.98%

Table 2: Estimated impact for a plan moving to a new annual limit

Current limit	New Limit				
	\$500k	\$750k	\$1 million	\$1.5 million	\$2 million
\$250k	3.71%	5.12%	6.11%	7.00%	7.63%
\$500k		1.35%	2.31%	3.17%	3.77%
\$750k			0.95%	1.79%	2.39%
\$1 million				0.83%	1.43%
\$1.5 million					0.59%

Table 3: Population that would exceed the annual limit

threshold	percent of insured population who would exceed
\$500,000	0.063%
\$750,000	0.043%
\$1,000,000	0.033%
\$1,500,000	0.026%
\$2,000,000	0.019%

Table 4: Cumulative increase averaged across the markets for the 3 years

		500k	750k	\$1 million	\$1.5 million	\$2 million
Large	Year1	0.00%	0.00%	0.00%	0.01%	0.02%
	Year2	0.00%	0.00%	0.00%	0.02%	0.03%
	Year3+	0.00%	0.00%	0.00%	0.02%	0.04%
Small	Year1	0.01%	0.02%	0.03%	0.07%	0.09%
	Year2	0.01%	0.03%	0.06%	0.11%	0.16%
	Year3+	0.02%	0.04%	0.07%	0.15%	0.20%
Individual	Year1	0.01%	0.02%	0.03%	0.09%	0.13%
	Year2	0.01%	0.03%	0.05%	0.15%	0.22%
	Year3+	0.01%	0.04%	0.07%	0.19%	0.28%

From: [Baum, Beth - EBSA](#)
To: [Baum, Beth - EBSA](#); [Benson, Susanna - SOL](#); [Butikofer, James - EBSA](#); [Corrigan, Dara \(HHS/OHR\)](#); [Cosby, Chris - EBSA](#); [Helen.Morrison@do.treas.gov](#); [Karen Levin - HOME](#); [Knopf Kevin - OTP](#); [Kosin, Donald \(HHS/OGC\)](#); [Levin Karen](#); [Mayhew, James A. \(CMS/CPC\)](#); [Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV](#); [Schumacher, Elizabeth - EBSA](#); [Tawshunsky Alan](#); [Taylor, William - SOL](#); [Turner, Amy - EBSA](#); [Stafford, Leslie \(HHS/OGC\)](#); [Dailey, Joan \(HHS/OGC\)](#)
Subject: Plan for Tomorrow
Date: Thursday, June 03, 2010 5:39:44 PM
Attachments: [Pkg of 6 Reg Text 6.3.10 1030am.doc](#)
[Pkg of 6 Joint Preamble 6.3.10 1030am.doc](#)

Let's meet at 930am tomorrow and we will take an early lunch break from 1130-1230 for DOL's clearance briefing.

We'll start with 2719A. I am attaching a draft omnibus reg text and draft joint preamble for the "package of 6" (2704, 2711, 2712, 2716, 2719A, and 2722). Amy will do some work and circulate some language (later tonight) on the decisions that the principals have made on 2719A.

We are also expecting OMB passback on 1251 sometime tomorrow morning, so we may need to adjust the schedule to start addressing those comments.

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR HEALTH INSURANCE

PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 continues to read as follows:

Authority:

29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

Subpart B—Other Requirements

2. Section 2590.701-2 is amended by revising the definition of preexisting condition exclusion to read as follows:

§ 2590.701-2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion

includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

3. Section 2590.701-3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 2590.701-2 of this Part.

* * * * *

4. Section 2590.715-2714 is amended by revising paragraph (d) to read as follows:

(d) Uniformity irrespective of age.—(1) In general. Subject to paragraph (d)(2) of this section, the terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(2) Preexisting condition exclusions for children age 19 and older before 2014. For plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or health insurance coverage may impose a preexisting condition exclusion (consistent with the rules of section 2590.701-3 of this Part) on children who are age 19 or older even though this is prohibited with respect to children under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

5. Section 2590.715-2704 is added to Subpart C to read as follows:

§ 2590.715-2704 Prohibition of preexisting condition exclusions.

(a) In general. (1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701-2 of this Part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition. (The denial of an application for coverage based on a preexisting condition exclusion also violates PHS Act section 2702 (guaranteed availability of coverage) and PHS Act section 2705 (prohibition against discrimination based on health status) for policy years beginning on or after January 1, 2014.)

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13 year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13 year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13 year-old child.

6. Section 2590.715-2711 is added to Subpart C to read as follows:

(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(e) Transitional rules for individuals whose coverage ended by reason of reaching a lifetime limit.

(1) In general. The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage ended under a group health plan or group health insurance coverage by reason of reaching a lifetime limit on the dollar value of all benefits for any individual the availability of dependent coverage of children ended before the attainment of age 26 (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for coverage under a group health plan or group health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) Opportunity to enroll required. (i) If a group health plan, or group health insurance coverage, in which an individual described in paragraph (e)(1) of this section is eligible to enroll (or is required to become eligible to enroll) is the plan or coverage in which the individual's coverage ended (or did not begin) for the reasons described in paragraph (e)(1)(i) of this section, and if the plan, or the issuer of such coverage, is subject to the requirements of this section, the plan and the issuer are required to give the child an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This opportunity (including the written notice) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The written notice must include a statement that any individual whose coverage ended by reason of reaching a lifetime limit on the dollar value of all benefits is eligible to enroll in the plan or coverage. The notice may be provided to an employee on behalf of the employee's dependent. In addition, the notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. If a notice satisfying the requirements of this paragraph (e)(2) is provided to an employee whose dependent is entitled to an enrollment opportunity under this paragraph (e), the obligation to provide the notice of enrollment opportunity under this paragraph (e)(2) with respect to that dependent is satisfied for both the plan and the issuer.

(3) Effective date of coverage. In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §2590.701-6(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) Examples. The rules of this paragraph (e) are illustrated by the following examples:

Comment [blb1]: Need to revise – these are from 2714.

Example 1. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan allows children of employees to be covered under the plan until age 19, or until age 23 for children who are full-time students. Individual B, an employee of Y, and Individual C, B's child and a full-time student, were enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, C turns 23 years old and loses dependent coverage under Y's plan. On or before January 1, 2011, Y's group health plan gives B written notice that individuals who lost coverage by reason of ceasing to be a dependent before attainment of age 26 are eligible to enroll in the plan, and that individuals may request enrollment for such children through February 14, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this paragraph (f) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan allows children of employees to be covered under the plan until age 22. Individual D, an employee of Z, and Individual E, D's child, are enrolled in family coverage under Z's group

health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E turns 22 years old and ceases to be eligible as a dependent under Z's plan and loses coverage. D drops coverage but remains an employee of Z.

(ii) Conclusion. In this Example 2, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) Facts. Same facts as Example 2, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 4. (i) Facts. Same facts as Example 2, except that E elected COBRA continuation coverage.

(ii) Conclusion. In this Example 4, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll other than as a COBRA qualified beneficiary (and must provide, by that date, written notice of the opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 5. (i) Facts. Employer X maintains a group health plan with a calendar year plan year. Prior to 2011, the plan allows children of employees to be covered under the plan until the child attains age 22. During the 2009 plan year, an individual with a 22-year old child joins the plan; the child is denied coverage because the child is 22.

(ii) Conclusion. In this Example 5, notwithstanding that the child was not previously covered under the plan, the plan must provide the child, not later than January 1, 2011, an opportunity to enroll (including written notice to the employee of an opportunity to enroll the child) that continues for at least 30 days, with enrollment effective not later than January 1, 2011.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

7. Section 2590.715-2712 is added to Subpart C to read as follows:

§ 2590.715-2712 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission.

(3) The rules of this paragraph (a) are illustrated by the following example:

Example. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A was treated for acne six years ago. A is later diagnosed with breast cancer and seeks benefits

under the plan. On or around the same time, the issuer receives information about A's prior treatment for acne, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example, the plan cannot rescind A's coverage because A's failure to disclose the prior treatment for acne was not fraudulent or an intentional misrepresentation of material fact.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage, including the requirement under PHS Act section 2719(a)(1)(C), which requires a plan or an issuer to allow an enrollee to continue coverage pending the outcome of an appeal of a coverage or claim determination.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

8. Section 2590.715-2716 is added to Subpart C to read as follows:

§ 2590.715-2716 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code that apply to self-insured medical reimbursement plans (prohibiting discrimination in favor of highly compensated individuals as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-

insured plan) under this section as if the group health plan were a self-insured medical reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

6. Section 2590.715-2719A is added to Subpart C to read as follows:

(a) Choice of Health Care Professional. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer shall permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept such individual.

(b) Coverage of Emergency Services.—(1) In general. If a group health plan, or a health insurance issuer offering group or individual health insurance issuer, provides or covers any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(ii))—

(i) without the need for any prior authorization determination;

(ii) whether the health care provider furnishing such services is a participating provider with respect to such services;

(iii) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee—

(A) by a nonparticipating health care provider with or without prior authorization; or

(B)(1) such services will be provided without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services does not have a contractual relationship with the plan for the providing of services that is more restrictive than the requirements or limitations that apply to emergency department services received from providers who do have such a contractual relationship with the plan; and

(2) if such services are provided out-of-network, the cost-sharing requirement (expressed as a copayment amount or coinsurance rate) is the same requirement that would apply if such services were provided in-network;

(iv) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of ERISA, or section 9801 of the Internal Revenue Code, and other than applicable cost-sharing).

(2) Definitions. In this subsection:

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(ii) Emergency services. The term emergency services means, with respect to an emergency medical condition –

(A) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient.

(iii) Stabilize. The term to stabilize, with respect to an emergency medical condition (as defined in paragraph (b)(2)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) Access to pediatric care.—(1) Pediatric care. In the case of a person who has a child who is a participant, beneficiary, or enrollee under a group health plan, or health insurance coverage offered by a health insurance issuer in the group or individual market, if the plan or issuer requires or provides for the designation of a participating primary care provider for the child, the plan or issuer shall permit such person to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if such provider participates in the network of the plan or issuer.

(2) Construction. Nothing in paragraph (c)(1) of this section shall be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(3) Examples. The rules of this paragraph (c) are illustrated by the following examples:

Example 1. (i) Facts. An HMO designates for each enrollee a physician who specializes in internal medicine to serve as the primary care provider for the enrollee and the enrollee's family. Enrollee A requests that Pediatrician B be designated as the primary care provider for her child. Pediatrician B is a participating provider in the HMO's network.

(ii) Conclusion. In this Example 1, the HMO must permit Enrollee A's designation of Pediatrician B as the primary care provider for Enrollee A's child in order to comply with the requirements of this section (c).

Example 2. (i) Facts. Same facts as Example 1 except that Enrollee A takes her child to Pediatrician B for treatment of the child's severe peanut allergies. Pediatrician B wishes to refer Enrollee A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies not does it have an allergist participating in its network.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this section (c) since the exclusion of treatment for food allergies was in accordance with the terms of Enrollee A's coverage.

Example 3. (i) Facts. Same facts as Example 1 except that Enrollee A wishes to designate as a primary care provider for her child a pediatrician who is an Allopathic Physician (MD). Only pediatricians who are Doctors of Osteopathic Medicine (DO), however, participate in HMO's network.

(ii) Conclusion. In this Example 3, the HMO has not violated the requirements of this section (c) since Enrollee A can still designate a participating pediatrician as the primary care provider for her child. The fact that there are no pediatricians who are Allopathic Physicians who participate in the HMO's network does not violate this section (c).

(d) Patient access to obstetrical and gynecological care—(1) General rights—(i) Direct access. A group health plan or health insurance issuer offering group or individual health insurance coverage, described in paragraph (d)(2) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider described in paragraph (d)(2)(ii) of this section) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. Such professional shall agree to otherwise adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(ii) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (d)(2) of this section shall treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (d)(1)(i) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(2) Application of paragraph. A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in this paragraph is a group health plan or coverage that—

(i) provides coverage for obstetric or gynecological care; and

(ii) requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(3) Construction. Nothing in paragraph (d)(1) of this section shall be construed to—

(i) waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(ii) preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(e) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

10. 2722: HHS Opt-out Reg:

9. Section 146.180 is amended as follows:

- A. Revising paragraph (a)(1).
- B. Adding a new paragraph (a)(2).
- C. Renumbering paragraphs (a)(2), (a)(3) and (a)(4) as (a)(3), (a)(4) and (a)(5), respectively.
- D. Replacing “2706” with “2727” each place it appears in paragraph (a)(1)(i)(F) and in Example 1 of paragraph (a)(3) (previously designated as (a)(2)).
- E. Making a conforming change to paragraph (a)(4)(i) (previously designated as (a)(3)(i)).
- F. Updating paragraph (c) to reflect the current address to which exemption elections may be mailed and providing a facsimile number to which elections may be faxed as an alternative to mailing elections.
- G. Removing the outdated parenthetical reference to § 146.125(a)(2) in paragraph (f)(2)(ii).
- H. Making a conforming change to paragraph (f)(3)(i).
- I. Adding a conforming sentence at the end of Example 1 in paragraph (h)(4)(i).
- J. Updating Example 4 in paragraph (i)(2)(iv).

The revisions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) Requirements subject to exemption—(1) Non-collectively bargained plans. (i) Plan years commencing before September 23, 2010. A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), for plan years commencing before September 23, 2010, from any or all of the following requirements:

- (A) Limitations on preexisting condition exclusion periods described in § 146.111.
- (B) Special enrollment periods for individuals and dependents described in § 146.117.

(C) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements in § 146.121(a)(1)(vi) and § 146.122 that prohibit discrimination with respect to genetic information.

(D) Standards relating to benefits for mothers and newborns described in § 146.130.

(E) Parity in the application of certain limits to mental health benefits described in § 146.136.

(F) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2727 of the PHS Act.

(G) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(ii) Plan years beginning on or after September 23, 2010. (i) A sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan for plan years beginning on or after September 23, 2010, only from any or all of the requirements described in paragraph (a)(1)(i)(D), (E), (F) or (G). With respect to those plan years, the notices required by paragraph (f) of this section must reflect the limitations set forth in this paragraph (a)(1)(ii).

(iii) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1)(i). The plan year commences September 1 each year. The plan is not subject to the limitations of paragraph (a)(1)(ii) until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(iv) Example 2. Same facts as in Example 1, except the plan year commences October 1 each year. The plan is subject to the limitations of paragraph (a)(1)(ii) beginning with the plan year that commences on October 1, 2010. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(2) Collectively bargained plans. (i) Special rule. Without regard to paragraph (b)(2) of this section, a group health plan that is governed by a collective bargaining agreement that was ratified before March 23, 2010, is subject to the limitations set forth in paragraph (a)(1)(ii) beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement. The notices required by paragraph (f) of this section, with respect to the first plan year subject to the limitations of paragraph (a)(1)(ii), must reflect those limitations.

(ii) Example. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1)(i) of this section. The collective bargaining agreement applies to five plan years, October 1, 2007 through September 30, 2012. For the plan year that commences on October 1, 2012, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1)(i)(A), (B) and (C). Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(3) Limitations. * * *

(A) Example 1. A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must

cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

* * *

(4) Stop-loss or excess risk coverage. For purposes of this section—(i) Subject to paragraph (a)(4)(ii), * * *

(5) Construction. * * *

* * * * *

(c) Mailing address. The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Medicare Enrollment and Appeals Group, CPC, ATTN: HIPAA Opt-Out, 7500 Security Boulevard, C2-12-16, Baltimore, MD 21244-1850. Alternatively, the plan sponsor may fax the exemption election to 410-786-8001.

* * * * *

(f) * * *

(2) * * *

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, * * *

(3) * * *

(i) The specific requirements described in paragraphs (a)(1) or (a)(2) of this section, as applicable, from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

* * * * *

(h) * * *

(4) * * *

(i) Example 1. (A) * * *

(B) * * * However, regarding plan years that begin on or after September 23, 2010, the plan sponsor no longer can elect to exempt its plan from prohibitions against enrollment discrimination based on health status-related factors.

* * *

(i) * * *

(2) * * *

(iv) Example 4: A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from the requirements of paragraph (a)(1)(i)(E) of this section. The collective bargaining agreement applies to five plan years, 2007 through 2011. For the first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2007 through December 31, 2011. Prior to the dissemination of the annual notice for the 2010 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2007 through December 31, 2011. Accordingly, CMS would not invalidate the election for the 2010 plan year.

[Billing Codes: 4830-01-P; 4510-29-P; 4120-01-P]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 54 and 602

TD

RIN 1545-XXXX

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-XXXX

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

OCIIO-XXXX-IFC

45 CFR Part 147

RIN XXXX-XXXX

Interim Final Rules for Group Health Plans and Health Insurance Issuers under the Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, discrimination in favor of highly compensated individuals, patient protections, and non-federal governmental plans.

DATES: Effective date. These interim final regulations are effective on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Comment date. Comments are due on or before **[INSERT DATE 90 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Applicability date. These interim final regulations generally apply to group health plans and group health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**. These interim final regulations generally apply to individual health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB42, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Email: [E-OHPSCA\[XXXX\].EBSA@dol.gov](mailto:E-OHPSCA[XXXX].EBSA@dol.gov).

- Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: RIN 1210-AB42.

Comments received by the Department of Labor will be posted without change to www.regulations.gov and www.dol.gov/ebsa, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIO-9991-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.
2. By regular mail. You may mail written comments to the following address ONLY:
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services,
Attention: OCIO-9991-IFC,
P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Office of Consumer Information and Insurance Oversight,
Department of Health and Human Services,
Attention: OCIIO-9991-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Office of Consumer Information and Insurance Oversight,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A

stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard,

Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-118412-10, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: CC:PA:LPD:PR (REG-118412-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-118412-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786-1565.

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's website (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website

(http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp) and information on health reform can be found at <http://www.healthreform.gov>..

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of part A of title XXVII of the PHS Act applicable under ERISA and the Code to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if those provisions of the PHS Act were included in ERISA and the Code. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The

¹ The term “group health plan” is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term “health plan”, as used in other provisions of title I of the Affordable Care Act. The term “health plan” does not include self-insured group health plans.

preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of the Affordable Care Act are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers stricter requirements than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations implementing the revised PHS Act sections 2701 through 2719A in several phases. The first publication in this series was a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). The second publication was interim final regulations implementing PHS Act section 2714 (requiring dependent coverage of children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third publication was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on May XX, 2010 (75 FR XXXXX). These interim final regulations are being published to implement PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding rescissions), 2716 (prohibiting discrimination in favor of highly compensated individuals), 2719A (regarding patient protections), and 2722 (regarding the application of the Affordable Care Act provisions to nonfederal governmental plans). PHS

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

Act section 2704 generally is effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014. However, with respect to enrollees, including applicants for enrollment, who are under 19 years of age, PHS Act section 2704 is effective for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.³ The rest of these provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

II. Overview of the Regulations:

A. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815-2704, 29 CFR 2590.715-2704, 45 CFR 147.108)

Section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA⁴ rules relating to preexisting condition exclusions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under certain circumstances. The Affordable Care Act provision prohibits any preexisting condition exclusions imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan

³ Section 1255 of the Affordable Care Act. See also section 10103(e)-(f) of the Affordable Care Act.

⁴ HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

years (in the individual market, policy years) beginning on or after September 23, 2010.

HIPAA generally defines a preexisting condition exclusion⁵ as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

For group health plans and group health insurance issuers, a denial of coverage of an individual based on a preexisting condition exclusion also violates the HIPAA rules prohibiting discrimination based on a health factor. Beginning on January 1, 2014, a denial of coverage of an individual based on a preexisting condition would also violate more than one provision in the individual market: the prohibition against preexisting condition exclusions, the guaranteed availability requirement, and the prohibition against discrimination based on health status. Of course, if an individual was denied coverage beginning in 2014 on a ground other than the existence of a preexisting condition or a health factor, the denial would only violate the right to guaranteed availability.

The protections in the new PHS Act section 2704 generally apply to plan years (in the individual market, policy years) beginning on or after January 1, 2014. The Affordable Care Act provides, however, that these protections apply with respect to enrollees under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. An enrollee under age 19 thus could not be denied benefits based on a preexisting condition. In

⁵ Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1); after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1). See also ERISA section 701(b)(1) and Code section 9801(b)(1).

order for an individual to receive the same protection that applies in the case of such an enrollee, the individual similarly could not be denied benefits (in whole or part) based on a preexisting condition. Thus, for plan years (in the individual market, for policy years) beginning on or after September 23, 2010, PHS Act section 2704 protects individuals under age 19 with a preexisting condition from being denied coverage under a plan (in whole or part) based on the preexisting condition.

These interim final regulations do not change the HIPAA rule that a plan's or issuer's exclusion of benefits for a condition from the plan or policy regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. This point is still relevant for these interim final regulations and is illustrated with examples in the HIPAA regulations on preexisting condition exclusions.⁶ (Other requirements of Federal or State law, however, may prohibit certain benefit exclusions.)

The interim final regulations under PHS Act section 2714 (relating to the continuation of dependent coverage until age 26)(75 FR 27122, May 13, 2010) provide that the terms of a plan or policy for dependent coverage cannot vary based on the age of a child, except for children age 26 or older. These interim final regulations amend those regulations to clarify that, for plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or policy may impose a preexisting condition exclusion (consistent with the rules of 26 CFR 54.9801-3, 29 CFR 2590.701-3, and 45 CFR 146.111) on children who are age 19 or older even though this is prohibited with respect to children under age 19.

Application to grandfathered health plans. Under the statute and these interim final regulations, a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a

⁶ See Examples 6, 7, and 8 in 26 CFR 54.9801-3(a)(1)(ii), 29 CFR 701-3(a)(1)(ii), 45 CFR 146.111(a)(1)(ii).

grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704. See 26 CFR 54.9815-1251, 29 CFR 2590.715-1251, and 45 CFR 147.140 regarding status as a grandfathered health plan.

B. PHS Act Section 2711, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815-2704, 29 CFR 2590.715-2704, 45 CFR 147.108)

Section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits. However, these interim final regulations provide that the annual limit rules do not apply to health flexible spending arrangements.⁷

The statute also allows “restricted annual limits” with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. In addition, the statute provides that, with respect to benefits that are not essential health benefits, a plan or issuer may impose annual or lifetime per individual limits on specific covered benefits. Rather than provide a definition of “essential health benefits,” these interim final regulations cross-reference section 1302(b) of the Affordable Care Act and applicable regulations.⁸

These interim final regulations clarify that the prohibition under PHS Act section 2711 does not prevent a plan or issuer from excluding all benefits for a condition, but if any benefits are provided for a condition, then the requirements of the rule apply. Therefore, an exclusion of all benefits for a condition is not considered to be an annual or lifetime dollar limit.

⁷ Section 9005 of the Affordable Care Act specifically limits the annual amount of salary reduction contributions for health flexible spending arrangements.

⁸ Regulations under section 1302(b) of the Affordable Care Act have not yet been issued.

The statute and these interim final regulations provide that for plan years (in the individual market, policy years) beginning before January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may only establish a restricted annual limit on the dollar value of essential health benefits. The statute provides that in defining the term “restricted annual limit,” the Departments “ensure that access to needed services is made available with a minimal impact on premiums.”

In establishing the restricted annual limit, the Departments considered several factors: (1) the current use of annual limits in the group and individual market; (2) the average premium impact of imposing different annual limits on the individual, small group, and large group markets; (3) the number of individuals who will continue to have annual medical expenses that exceed an annual limit; and (4) the possibility that a plan or issuer would switch to an annual limit when lifetime limits are prohibited.

Approximately four percent of large employer plans, eight percent of small employer PPO plans, and 19 percent of individual market plans currently have annual limits. Although available data show that very few health insurance plans impose annual limits, at least half of small group plans and over 75 percent of policies in the individual market impose lifetime limits. The 2009 Kaiser Family Foundation/HRET Survey of Employers found that less than one percent of covered workers had lifetime limits less than \$1 million, 16 percent had limits between \$1 million and \$1.99 million, 43 percent had lifetime limits of \$2 million or more, and 41 percent had no lifetime maximum.⁹ Of those enrollees in indemnity plans with lifetime limits, 63 percent of single enrollees and 44 percent of family enrollees had lifetime maximums less than \$2 million while less than one percent of enrollees in network-based arrangements,

⁹ See the Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), at <http://ehbs.kff.org/pdf/2009/7936.pdf>.

such as HMOs, PPOs, or high deductible health plans with savings options had lifetime maximums less than \$2 million. While it is possible that those plans with lifetime limits will switch to annual limits prior to the elimination of annual limits in 2014, group health plans and health insurance issuers could use a number of changes to benefit design to mitigate any potential premium increases.

In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, these interim final regulations adopt a three-year phased approach for restricted annual limits. This phased-in approach provides ample opportunity for plans with relatively low annual limits (e.g., \$100,000, \$250,000, or \$500,000) to more gradually make adjustments that might smooth any increase in costs that might result from the increased minimum annual limits under these interim final regulations. The proposed annual limit levels ensure that the vast majority of individuals who may experience high medical costs during the year will continue to have access to coverage.

These interim final regulations provide the following minimum amounts for annual limits on the dollar value of benefits that are essential health benefits for plan years (in the individual market, policy years) beginning before January 1, 2014:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, \$750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, \$1.25 million; and
- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2 million.

Comment [b1]: Can we get rid of this whole paragraph? Cross reference the discussion in the economic analysis that goes over these same statistics?

If not, use cite for the 1st sentence from economic analysis cite to Mercer survey (FN 31 in old draft)

As these are minimums for plan years (in the individual market, policy years) beginning before 2014, plans or issuers may always use higher annual limits or impose no limits. Plans and policies with plan or policy years that begin between September 23 and December 31 have more than one plan or policy year under which the \$2 million minimum annual limit is available; however, a plan or policy generally may not impose an annual limit for a plan year beginning after December 31, 2013.

The minimum annual limits for plan or policy years beginning before 2014 apply on an individual-by-individual basis. Thus, any overall annual dollar limit on benefits applied to families may not operate to deny a covered individual the minimum annual benefits for the plan year (in the individual market, policy year). These interim final regulations clarify that, in applying annual limits for plan years (in the individual market, policy years) beginning before January 1, 2014, the plan (or policy) may only take into account essential health benefits.

These interim final regulations provide an enrollment (in the individual market, reinstatement) opportunity for individuals who reached their lifetime limits in a group health plan or health insurance coverage and remain otherwise eligible for the coverage. In the individual market, this reinstatement opportunity does not apply to individuals who reached their lifetime limits in individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in a family policy in the individual market while other family members remain in the coverage. This opportunity must be made available no later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. See discussion of transitional rules in Section II.G. of this preamble.

Application to grandfathered health plans. The statute and these interim final regulations relating to the prohibition on lifetime limits apply to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the prohibition on annual limits, including the special rules regarding restricted annual limits for plan years beginning before January 1, 2014, apply to group health plans and group health insurance coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage.

C. PHS Act Section 2712, Rescissions (26 CFR 54.9815-2712, 29 CFR 2590.715-2712, 45 CFR 147.2712)

PHS Act section 2712 provides rules regarding rescissions¹⁰ of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard applies to all rescissions, whether in the group or individual insurance market, or self-insured coverage. These rules also apply regardless of any contestability period of the plan or issuer.

These interim final regulations include several clarifications regarding the standards for rescission. First, these interim final regulations clarify that the rules of PHS Act section 2712 apply whether the rescission applies to a single individual or an entire group of individuals. Thus, for example, if an issuer attempted to rescind coverage of an entire employer group based

¹⁰ For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission.

on the actions of an individual within the group, the standards of these interim final regulations would apply. Second, these interim final regulations clarify that the rules of PHS Act section 2712 apply to representations made by the individual or a person seeking coverage on behalf of the individual. Thus, if a plan sponsor seeks coverage from an issuer for an entire employment-based group and makes representations, for example, regarding the prior claims experience of the group, the standards of these interim final regulations would also apply. Finally, PHS Act section 2712 refers to acts or practices that constitute fraud. These interim final regulations clarify that, to the extent that an omission constitutes fraud, that omission would permit the plan or issuer to rescind coverage under this section. An example in these interim final regulations illustrates the application of the rule to misstatements of fact that are inadvertent.

PHS Act section 2712 adds a new advance notice requirement when coverage is rescinded where still permissible. Specifically, the second sentence in section 2712 provides that coverage may not be cancelled unless prior notice is provided, and then only as permitted under PHS Act sections 2702(c) and 2742(b). Under these interim final regulations, even if prior notice is provided, rescission is only permitted in cases of fraud or an intentional misrepresentation of a material fact as permitted under the cited provisions.¹¹ While this reference appears redundant, it is consistent with the first sentence.

These interim final regulations provide that a group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 days advance notice to

¹¹ The reference to section 2702(c) appears to be incorrect. After the amendments made by the Affordable Care Act, PHS Act section 2702(c) addresses network requirements for guaranteed availability of coverage. It seems more likely that the intended cross-reference is to new PHS Act section 2703(b), relating to nonrenewal of coverage in the group market, which corresponds to the other cross-reference, in PHS Act section 2742(b), to nonrenewal of coverage in the individual market. Both these provisions contain the fraud and intentional misrepresentation of material fact standard included in the first sentence of section 2712. In order to avoid confusion, these interim final regulations apply the fraud and misrepresentation standard found in sections 2703(b) and 2742(b).

an individual before coverage may be rescinded.¹² The notice must be provided regardless of whether the rescission is of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group.

These interim final regulations also clarify that other requirements of Federal or State law may apply in connection with a rescission of coverage, including the requirement under PHS Act section 2719(a)(1)(C), which requires a plan or an issuer to allow an enrollee to continue coverage pending the outcome of an appeal of a coverage or claim determination. Regulatory guidance regarding the provisions of PHS Act section 2719 is expected to be issued in the near future.

Application to grandfathered health plans. The rules regarding rescissions and advance notice apply to all grandfathered health plans.

D. PHS Act Section 2716, Prohibiting Discrimination in Favor of Highly Compensated Individuals (26 CFR 54.9815-2716, 29 CFR 2590.715-2716, 45 CFR 147.2716)

PHS Act section 2716 and these interim final regulations incorporate the nondiscrimination rules of section 105(h) of the Code and apply them to group health plans that are not self-insured plans. Section 105(h) generally prohibits self-insured medical reimbursement plans from discriminating in favor of highly compensated individuals in eligibility classifications or in benefits. Section 105(b) of the Code generally excludes from an employee's income (otherwise subject to federal income taxation) amounts received as reimbursement of medical care expenses for the employee or the employee's spouse, dependents, or children who have not attained age 27 by the end of the taxable year. If a self-insured medical reimbursement plan does not comply with the requirements of section 105(h), the general

¹² Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

exclusion from income (and hence, from federal income taxation) under section 105(b) does not apply with respect to highly compensated individuals. Highly compensated individuals are defined in section 105(h).

PHS Act section 2716 and these interim final regulations incorporate the substantive nondiscrimination requirements of Code section 105(h) but not the tax sanctions. An insured group health plan failing to comply with the nondiscrimination requirements of Code section 105(h) is subject to the sanctions and remedies that generally apply for a plan failing to comply with the requirements of chapter 100 of the Code (generally, an excise tax of \$100 per day per individual for each day the plan does not comply with the requirement), part 7 of ERISA (a civil action to enjoin a noncompliant act or practice or for appropriate equitable relief), or Title XXVII of the PHS Act (civil money penalties of \$100 per day per individual for each day the plan does not comply with the requirement). Thus, if a self-insured plan fails to comply with Code section 105(h), highly compensated individuals lose a tax benefit; if an insured group health plan fails to comply with Code section 105(h), the plan is subject to a civil action to compel it to provide nondiscriminatory benefits and the plan or plan sponsor is subject to an excise tax or civil money penalty of \$100 per day per individual. Rather than restate the rules under section 105(h) of the Code, these interim final regulations incorporate by reference those rules and applicable regulations.

Application to grandfathered health plans. The rules prohibiting discrimination in favor of highly compensated individuals do not apply to grandfathered health plans (but the rules of Code section 105(h) continue to apply to self-insured plans).

E. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815-2716, 29 CFR 2590.715-2716, 45 CFR 147.XXX)

F. PHS Act Section 2722, Patient Protections (45 CFR 147.XXX)

G. Individual Market and Non-Federal Governmental Plan Reforms

1. References to the Public Health Service Act

Conforming changes to references to sections of Title XXVII of the PHS Act are made throughout Parts 144 and 146 to reflect the renumbering of certain sections by the Affordable Care Act.

2. Definitions (45 CFR 144.103)

These interim final regulations define “policy year” as the 12-month period that is designated in the policy documents of individual health insurance coverage. If the policy document does not designate a policy year (or no such document exists), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year. The Affordable Care Act uses the term “plan year” in referring to the period of coverage in both the individual and group health insurance markets. The term “plan year,” however, is generally recognized as having only relevance in the group health insurance market. Accordingly, these interim final regulations substitute the term “policy year” for “plan year” in defining the period of coverage in the individual health insurance market.

These interim final regulations revise the definition of “preexisting condition exclusion” to clarify that the denial of an application for coverage because of a preexisting condition in the individual health insurance market is a preexisting condition exclusion. This definition at 45 CFR 144.103 is cross-referenced in both 45 CFR 146.111(a)(1) and 45 CFR 147.2704, and it

applies in both the group and individual health insurance markets, and also to entities that provide coverage to Federally eligible individuals.

3. Treatment of Non-Federal Governmental Plans (45 CFR 146.180)

The Affordable Care Act made numerous changes to Title XXVII of the PHS Act, including to section 2721(b)(2), which permitted the sponsor of a self-funded non-Federal governmental plan, as defined in 45 CFR 144.103, to elect to exempt the plan from certain requirements of Title XXVII of the PHS Act. This is referred to herein as the “opt-out provision.” Section 1001(4) of the Affordable Care Act re-designated section 2721 as section 2735. Section 1562(b)(12) of the Affordable Care Act amended section 1001(4) by re-designating section 2735(b)(2) as section 2722(a)(2).

Additionally, section 1562(a)(2) of the Affordable Care Act further amended the opt-out provision in §2722 by adding a new subparagraph (a)(2)(E), which prohibits a sponsor of a self-funded non-Federal governmental plan from electing to exempt the plan from the Subparts I and II in Part A of the revised Title XXVII. Subpart I (“General Reform”) contains the provisions of the original Subpart 1 of Part A of title XXVII of the PHS Act. The requirements in the original Subpart 1 included limitations on preexisting condition exclusion periods, special enrollment periods and prohibitions against discriminating against individual participants and beneficiaries based on health status. Because of the prohibition in PHS Act section 2722(a)(2)(E), self-funded non-Federal governmental plans can no longer elect to be exempted from these provisions in Subpart I starting with plan years beginning on or after September 23, 2010.

Section 1001(2) of the Affordable Care Act redesignated sections 2704 through 2707 (which respectively set forth the provisions of the Newborns’ and Mothers’ Health Protection Act of 1996, the Mental Health Parity Act of 1996 (as amended by the Mental Health Parity and

Addiction Equity Act (2008)), the Women's Health and Cancer Rights Act of 1998, and Michelle's Law (2008)) as sections 2725 through 2728, respectively, which are contained in a revised Subpart 2, "Exclusion of Plans; Enforcement; Preemption." A sponsor of a self-funded non-Federal governmental plan may continue to elect to exempt its plan from the requirements of Subpart 2 (which is separate from Subpart II) of Part A of Title XXVII since the prohibition in section 2722(a)(2)(E) does not reference Subpart 2.

Section 1004 of the Affordable Care Act provides, in pertinent part, that the amendments made by section 1001 are "effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act[.]" The Affordable Care Act was enacted on March 23, 2010. Therefore, section 1001, as amended by section 1562(a) and (b)(12), is effective for group health plan years beginning on or after September 23, 2010. The Affordable Care Act makes no exception for plan years beginning on or after September 23, 2010 that are governed by a previously ratified collective bargaining agreement under which the plan sponsor has elected to exempt the self-funded plan from one or more requirements of Subpart 1. The grandfathering provision in section 1251(d) of the Affordable Care Act only applies to insured collectively bargained plans. Accordingly, without regard to a collective bargaining agreement, a sponsor of a self-funded non-Federal governmental plan that commences a new plan year on or after September 23, 2010 can no longer elect to exempt the plan from requirements of Subpart 1. An example in these interim final regulations illustrates this.

Section 146.180 is being revised to reflect changes made by the Affordable Care Act, to add conforming changes and to make certain additional changes unrelated to the Affordable Care Act, such as updating the address to which an opt-out election should be submitted, updating an example to reflect more recent dates, and removing outdated text.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, numerous provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Grandfathered health plans are exempt from many of these provisions while group health plans and group and individual health insurance coverage that are not grandfathered health plans must comply with them. The determination of whether a plan or health insurance coverage is a grandfathered health plan therefore could substantially affect the design of the plan or health insurance coverage.

The six-month period between the enactment of the Affordable Care Act and the applicability of many of the provisions affected by grandfather status would not allow sufficient time for the Departments to draft and publish proposed regulations, receive and consider comments, and draft and publish final regulations. Moreover, regulations are needed well in advance of the effective date of the requirements of the Affordable Care Act. Many group health plans and health insurance coverage that are not grandfathered health plans must make significant changes in their provisions to comply with the requirements of the Affordable Care Act. Moreover, plans and issuers considering other modifications to their terms need to know whether those modifications will affect their status as grandfathered health plans. Accordingly, in order to allow plans and health insurance coverage to be designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting

these regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact and Paperwork Burden

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

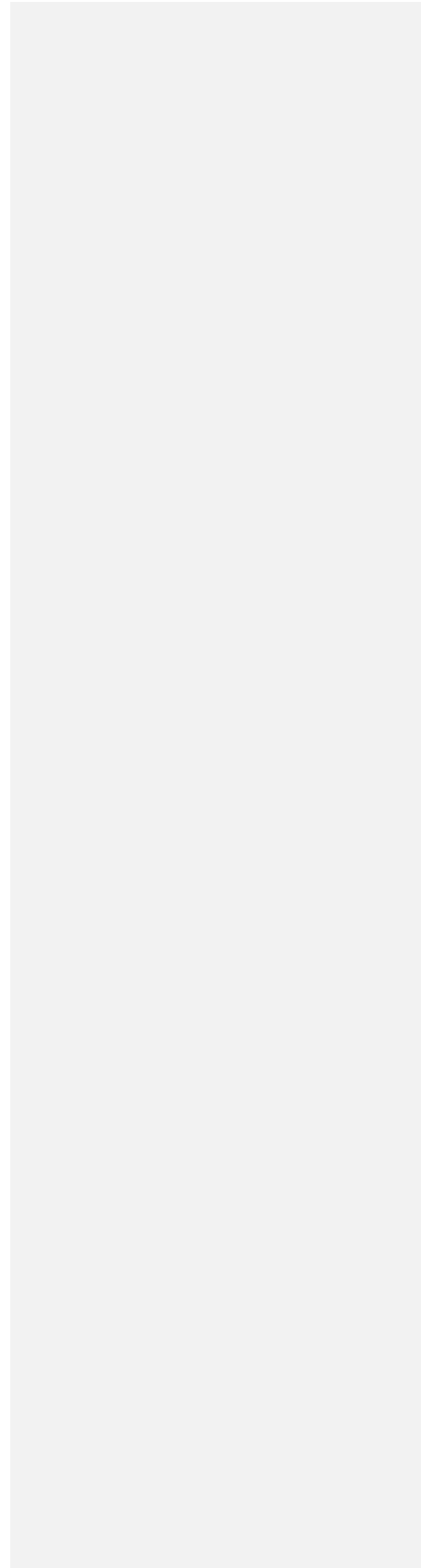
Steven T. Miller
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved:

Michael F. Mundaca
Assistant Secretary of the Treasury (Tax Policy).

Signed this _____ day of _____, 2010.

Phyllis C. Borzi
Assistant Secretary
Employee Benefits Security Administration
Department of Labor



Approved: _____

Jay Angoff,

Director,

Office of Consumer Information and Insurance
Oversight.

Approved: _____

Kathleen Sebelius,

Secretary, Department of Health and Human
Services.

From: [Mayhew, James A. \(CMS/CPC\)](#)
To: [Drobac, Krista \(HHS/OCIIO\)](#); [Larsen, Steven \(HHS/OCIIO\)](#)
Cc: [Wilson, Lisa \(HHS/OCIIO\)](#); [Blodgett, Bennett \(HHS/OCIIO\)](#)
Subject: RE: Groom Law Group analysis
Date: Wednesday, June 02, 2010 6:06:00 PM

I'll take a look at the paper.

-----Original Message-----

From: Drobac, Krista (HHS/OCIIO)
Sent: Wednesday, June 02, 2010 5:57 PM
To: Larsen, Steven (HHS/OCIIO); Mayhew, James A. (CMS/CPC)
Cc: Wilson, Lisa (HHS/OCIIO); Blodgett, Bennett (HHS/OCIIO)
Subject: FW: Groom Law Group analysis

Steve and Jim:

A friend of mine represents Aetna and called me about limited benefit plans. Attached is a legal analysis that was conducted for three industry trade groups -- National Retail Federation, Retail Industry Leaders Association, and the American Benefits Council -- with whom Aetna is working. The paper concludes that HHS has the authority to maintain annual limits for limited benefit plans.

As you know, we've been hearing from a lot of groups on this issue. Although limited benefit plans are of limited value to consumers, it's still considered "coverage" to consumers, and their premiums will skyrocket if the benefit limits are eliminated. Are we planning to address limited benefit plans in the reg? If not, we'll need to incorporate a robust set of talking points in our June 21st rollout about why this is good for consumers....because otherwise insurers will spin it that rates are going to increase significantly for the 5-10 million people currently holding these plans.

-Krista

-----Original Message-----

From: Elizabeth Barnett [<mailto:ebarnett@dcavenuesolutions.com>]
Sent: Wed 6/2/2010 5:36 PM
To: Drobac, Krista (HHS/OCIIO)
Subject: Groom Law Group analysis

Hi Krista,

Per our conversation about limited benefit plans, I wanted to share with you a Groom Law Group opinion to three trades (National Retail Federation, Retail Industry Leaders Association, and the American Benefits Council) that concludes that HHS has the authority to issue a special rule related to limited health benefit plans permitting them to maintain annual limits on essential benefits for plan years beginning prior to January 1, 2014. These trades are working with Aetna on this issue.

Let me know if you'd like a meeting or a call with the folks from Groom to get further clarification or ask questions. Thanks!

Elizabeth

Elizabeth MacDonald Barnett

Avenue Solutions

900 7th Street, NW

Suite 750

Washington, DC 20001

(202) 347-8724 (direct)

(202) 341-6598 (cell)

Email: ebarnett@dcavenuesolutions.com

Website: www.avenue-solutions.com

From: [OCIO ExecSec](#)
To: [Larsen, Steven \(HHS/OCIO\)](#); [Mayhew, James A. \(CMS/CPC\)](#)
Cc: [Cohen, Ken ES \(HHS/OCIO\)](#); [Files Flory, Ashley \(HHS/ASPE/HP\)](#); [Gurule, Roman \(CMS/OSORA\)](#); [Gurule, Roman \(HHS/OCIO\)](#)
Subject: Small Business Concil letter on annual limit
Date: Tuesday, June 01, 2010 5:00:21 PM
Attachments: [SBE Council on annual limit.pdf](#)

fyi

*** RECEIVED ***
May 31 2010 10:28:52 WS# 20
OSNUM: 053120101023
OFFICE OF THE SECRETARY
CORRESPONDENCE
CONTROL CENTER

Obtained by Judicial Watch July 11, 2011 through FOIA



Protecting Small Business, Promoting Entrepreneurship

May 28, 2010

The Honorable Kathleen Sebelius
Secretary
Department of Health & Human Services
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Fax: 202-690-7203

The Honorable Hilda Solis
Secretary
Department of Labor
Frances Perkins Building
200 Constitution Avenue, NW
Washington, DC 20210
Fax: 202-693-6111

Dear Secretary Sebelius and Secretary Solis:

Later this year, 1.4 million Americans who have good health coverage through "Limited Medical Benefit" plans may lose such coverage under the Patient Protection & Affordable Care Act (PPACA). The annual dollar limit provisions of PPACA governing group plans take effect for plan years beginning September 23, 2010, which means that these critical health plans may cease to be an option unless an exception is made for such coverage.

On behalf of the Small Business & Entrepreneurship Council (SBE Council) and our members who utilize limited medical benefit plans for their employees, I am requesting that the Department of Health and Human Services (HHS) make an exception for these plans, or clarify the law with respect to their status leading up to 2014 when annual dollar limits are fully prohibited under the new health care law.

Small to mid-size employers use these affordable plans for full or part-time hourly employees, those who work on a seasonal basis or may be fulfilling a waiting period for an employer's regular health plan. While termed "limited," such benefit plans are coveted by those who use them because they affordably cover most medical issues. They serve an important purpose in the market, and without these plans many workers would not have access to health coverage.

2944 Hunter Mill Road
Suite 204
Oakton, VA 22124

tel: 703.242.5840
fax: 703.242.5841

www.sbecouncil.org

15th Anniversary 1994 - 2009

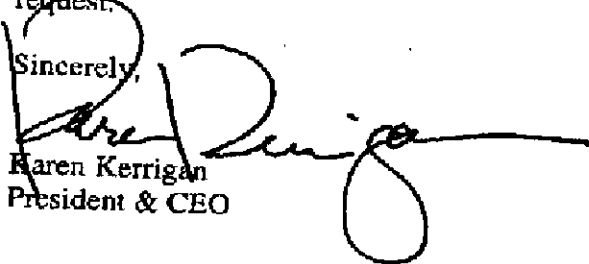
(page 2, Sebelius/Solis, LBPs)

Removing the annual dollar limits from these plans will drive costs significantly higher for small to mid-size employers. And as you know, the high costs associated with more comprehensive plans have made, and continue to make, health coverage unaffordable for many employers. It would be ironic indeed if 1.4 million workers lose health insurance as a result of a law that was intended to provide coverage to more Americans. But that will be the unintended consequence of PPACA unless HHS makes an exception for these plans, or clarifies the law.

SBE Council kindly requests that HHS quickly act on this matter. Immediate guidance is needed so that employers can properly plan "next steps" for their employees. As you well know, small businesses continue to face high health coverage costs. They, along with many in the general public, remain unconvinced that the new health care law will preserve the coverage they now offer while providing more choices at affordable rates. Uncertainty regarding limited benefit plans, and more specifically how the PPACA threatens coverage for 1.4 million employees, only fuels skepticism and worry.

Please do not hesitate to contact my office if you have questions, or if SBE Council can provide further assistance. Thank you, in advance, for considering our concerns and request.

Sincerely,


Karen Kerrigan
President & CEO

*** RECEIVED ***
May 31, 2010 10:28:52 WS# 20
OSNUM: 053120101023
OFFICE OF THE SECRETARY
CORRESPONDENCE
CONTROL CENTER

Obtained by Judicial Watch July 11, 2011 through FOIA



FAX TRANSMITTAL SHEET

DATE: May 28, 2010
TO: Honorable Secretary Kathleen Sebelius
FROM: Karen Kerrigan
FAX #: 202-690-7203

.....

SBE Council
2944 Hunter Mill Road
Suite 204
Oakton, VA 22124
703-242-5840
www.sbecouncil.org

Protecting Small Business, Promoting Entrepreneurship

From: [Baum, Beth - EBSA](#)
To: [Mayhew, James A. \(CMS/CPC\)](#)
Subject: RE: Preamble language
Date: Tuesday, June 01, 2010 11:10:52 AM
Attachments: [Joint Preamble 4.27.10 1pm.doc](#)

[I think this is the latest version.](#)

From: Mayhew, James A. (CMS/CPC) [mailto:James.Mayhew@cms.hhs.gov]
Sent: Tuesday, June 01, 2010 11:08 AM
To: Baum, Beth - EBSA
Subject: Preamble language

Beth-

Do you have the latest draft preamble of the large package before it was broken up? I have the regulation text (dated 4/27/10) but I can't find the preamble. If you do have it, could you forward it to me?

Thanks!

[Billing Codes: 4830-01-P; 4510-29-P; 4120-01-P]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

TD

RIN 1545-BJ46

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB41

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

OCIIO-

45 CFR Part 146

RIN 0938-

Interim Final Rules for Group Health Plans and Health Insurance Issuers under the

Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the requirements for group health plans and health insurance issuers in the group and individual markets under provisions of the Patient Protection and Affordable Care Act (the Affordable Care Act) regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, coverage of certain preventive health services without cost-sharing, coverage of dependent children to age 26, and discrimination in favor of highly compensated individuals. These interim final regulations also provide guidance on grandfathered health plans under the Affordable Care Act.

DATES: Effective date. These interim final regulations are effective on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Comment date. Comments are due on or before **[INSERT DATE 90 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Applicability date. These interim final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after September 23, 2010. These interim final regulations generally apply to individual health insurance issuers for policy years beginning on or after September 23, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines.

No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB41, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Email: E-OHPSCA.EBSA@dol.gov.

- Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: RIN 1210-AB41.

Comments received by the Department of Labor will be posted without change to www.regulations.gov and www.dol.gov/ebsa, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIO- . Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.
2. By regular mail. You may mail written comments to the following address ONLY:
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services,

Attention: OCIO- [REDACTED],

P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services,

Attention: OCIO- [REDACTED],

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to

leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the

headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-114494-10, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: CC:PA:LPD:PR (REG-114494-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-114494-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; [INSERT], Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at [INSERT].

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's website (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for

consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp).

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions in Part A of Title XXVII of the Public Health Service Act (PHS Act) relating to group health plans¹ and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of Part A of Title XXVII of the PHS Act applicable under ERISA and the Code to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if those provisions of the PHS Act were included in ERISA and the Code. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes. Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, specifies that certain plans or coverage existing as of the date of enactment (i.e., grandfathered health plans) are only subject to certain provisions.

¹ The term “group health plan”, which includes both insured and self-insured group health plans and is used in Title XXVII of the PHS Act, Part 7 of ERISA, and Chapter 100 of the Code, is distinct from the term “health plan” used in Title I of the Affordable Care Act, which does not include self-insured group health plans.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of Title XXVII of the PHS Act (changes of which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of the Affordable Care Act are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers stricter requirements than what is required by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) expect to issue regulations implementing the revised PHS Act sections 2701 through 2719A in several phases. The first publication in this series was a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the Federal Register on April 14, 2010 (75 FR 19297). This document contains interim final regulations implementing PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding rescissions), 2713 (requiring coverage of certain preventive health services without cost-sharing), 2714 (requiring dependent coverage of children to age 26), and 2716 (prohibiting discrimination in favor of highly compensated individuals). These interim final regulations also provide guidance on the rules of section 1251 of the Affordable Care Act regarding grandfathering of group health plans and health insurance coverage and on the requirement to provide enrollment opportunities to

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in Chapter 100 of the Code.

individuals who reached a lifetime limit or who lost or were not eligible for dependent coverage before age 26. These provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions in PHS Act sections 2701 through 2719A will be addressed in future regulations.

Because subtitles A and C of title I of the Affordable Care Act contain requirements that are applicable to both the group and individual health insurance markets, it would be duplicative to insert the requirements into both the existing 45 CFR Part 146 (Requirements for the Group Health Insurance Market) and 45 CFR Part 148 (Requirements for the Individual Health Insurance Market). Accordingly, these interim final regulations create a new Part 147 in Subchapter B of 45 CFR to implement these provisions of the Affordable Care Act. These provisions, to the extent that they apply to group health plans and group health insurance coverage, are also implemented under new provisions added to 29 CFR Part 2590 and 26 CFR Part 54.

II. Overview of the Regulations

A. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815-2704, 29 CFR 2590.715-2704, 45 CFR 147.2704)

Section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA³ rules relating to preexisting conditions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under

³ HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

certain circumstances. The Affordable Care Act provision prohibits any preexisting condition exclusions imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

HIPAA generally defines a preexisting condition exclusion⁴ as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

For group health plans and group health insurance issuers, a denial of coverage of an individual based on a preexisting condition exclusion also violates the HIPAA rules prohibiting discrimination based on a health factor. Beginning on January 1, 2014, a denial of coverage of an individual based on a preexisting condition would also violate more than one provision in the individual market: the prohibition against preexisting condition exclusions, the guaranteed availability requirement, and the prohibition against discrimination based on health status. Of course, if an individual was denied coverage beginning in 2014 on a ground other than the existence of a preexisting condition or a health factor, the denial would only violate the right to guaranteed availability.

⁴ Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1); after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1). See also ERISA section 701(b)(1) and Code section 9801(b)(1).

The protections in the new PHS Act section 2704 generally apply to plan years (in the individual market, policy years) beginning on or after January 1, 2014. The Affordable Care Act provides, however, that these protections apply with respect to enrollees under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. An enrollee under age 19 thus could not be denied benefits based on a preexisting condition. In order for an individual to receive the same protection that applies in the case of such an enrollee, the individual similarly could not be denied benefits (in whole or part) based on a preexisting condition. Thus, for plan years (in the individual market, for policy years) beginning on or after September 23, 2010, PHS Act section 2704 protects individuals under age 19 with a preexisting condition from being denied coverage under a plan (in whole or part) based on their preexisting conditions.

These interim final regulations do not change the HIPAA rule that a plan's or issuer's exclusion of benefits for a condition from the plan or policy regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. This point is still relevant for these interim final regulations and is illustrated with examples in the HIPAA regulations on preexisting condition exclusions.⁵ (Other requirements of Federal or State law, however, may prohibit certain benefit exclusions.)

Application to grandfathered health plans. A grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704. See 26 CFR 54.9815-2801, 29 CFR 2590.715-2801, and 45 CFR 147.2801 regarding grandfathered health plans.

⁵ See Examples 6, 7, and 8 in 26 CFR 54.9801-3(a)(1)(ii), 29 CFR 701-3(a)(1)(ii), 45 CFR 146.111(a)(1)(ii).

B. PHS Act Section 2711, No Lifetime or Annual Limits (26 CFR 54.9815-2711, 29 CFR 2590.715-2711, 45 CFR 147.2711)

Section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits. However, these interim final regulations provide that the annual limit rules do not apply to health flexible spending arrangements.⁶

The statute also allows “restricted annual limits” with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. In addition, the statute provides that, with respect to benefits that are not essential health benefits, a plan or issuer may impose annual or lifetime per individual limits on specific covered benefits. Rather than provide a definition of “essential health benefits,” these interim final regulations cross-reference section 1302(b) of the Affordable Care Act and applicable regulations.⁷

These interim final regulations clarify that the prohibition under PHS Act section 2711 does not prevent a plan or issuer from excluding all benefits for a condition, but if any benefits are provided for a condition, then the requirements of the rule apply. Therefore, an exclusion of all benefits for a condition is not considered to be an annual or lifetime dollar limit.

The statute and these interim final regulations provide that for plan years (in the individual market, policy years) beginning before January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may only establish a restricted annual limit on the dollar value of essential health benefits. The statute provides that

⁶ Section 9005 of the Affordable Care Act specifically limits the annual amount of salary reduction contributions for health flexible spending arrangements.

⁷ Regulations under section 1302(b) of the Affordable Care Act have not yet been issued.

in defining the term “restricted annual limit,” the Departments “ensure that access to needed services is made available with a minimal impact on premiums.”

In establishing the restricted annual limit, the Departments considered several factors: (1) the current use of annual limits in the group and individual market; (2) the average premium impact of imposing different annual limits on the individual, small group, and large group markets; (3) the number of individuals who will continue to have annual medical expenses that exceed an annual limit; and (4) the possibility that a plan or issuer would switch to an annual limit when lifetime limits are prohibited.

Approximately four percent of large employer plans, eight percent of small employer PPO plans, and 19 percent of individual market plans currently have annual limits. Although available data show that very few health insurance plans impose annual limits, at least half of small group plans and over 75 percent of policies in the individual market impose lifetime limits. The 2009 Kaiser Family Foundation/HRET Survey of Employers found that less than one percent of covered workers had lifetime limits less than \$1 million, 16 percent had limits between \$1 million and \$1.99 million, 43 percent had lifetime limits of \$2 million or more, and 41 percent had no lifetime maximum.⁸ Of those enrollees in indemnity plans with lifetime limits, 63 percent of single enrollees and 44 percent of family enrollees had lifetime maximums less than \$2 million while less than one percent of enrollees in network-based arrangements, such as HMOs, PPOs, or high deductible health plans with savings options had lifetime maximums less than \$2 million. While it is possible that those plans with lifetime limits will switch to annual limits prior to the elimination of annual limits in 2014, group health plans and

⁸ See the Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), at <http://ehbs.kff.org/pdf/2009/7936.pdf>.

health insurance issuers could use a number of changes to benefit design to mitigate any potential premium increases.

In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, these interim final regulations adopt a three-year phased approach for restricted annual limits. This phased-in approach provides ample opportunity for plans with relatively low annual limits (e.g., \$100,000, \$250,000, or \$500,000) to more gradually make adjustments that might smooth any increase in costs that might result from the increased minimum annual limits under these interim final regulations. The proposed annual limit levels ensure that the vast majority of individuals who may experience high medical costs during the year will continue to have access to coverage.

These interim final regulations provide the following minimum amounts for annual limits on the dollar value of benefits that are essential health benefits for plan years (in the individual market, policy years) beginning before January 1, 2014:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, \$750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, \$1.25 million; and
- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2 million.

As these are minimums for plan years (in the individual market, policy years) beginning before 2014, plans or issuers may always use higher annual limits or impose no limits. Plans and policies with plan or policy years that begin between September 23 and December 31 have more than one plan or policy year under which the \$2 million minimum annual limit is available;

however, a plan or policy generally may not impose an annual limit for a plan year beginning after December 31, 2013.

The minimum annual limits for plan or policy years beginning before 2014 apply on an individual-by-individual basis. Thus, any overall annual dollar limit on benefits applied to families may not operate to deny a covered individual the minimum annual benefits for the plan year (in the individual market, policy year). These interim final regulations clarify that, in applying annual limits for plan years (in the individual market, policy years) beginning before January 1, 2014, the plan (or policy) may only take into account essential health benefits.

These interim final regulations provide an enrollment (in the individual market, reinstatement) opportunity for individuals who reached their lifetime limits in a group health plan or health insurance coverage and remain otherwise eligible for the coverage. In the individual market, this reinstatement opportunity does not apply to individuals who reached their lifetime limits in individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in a family policy in the individual market while other family members remain in the coverage. This opportunity must be made available no later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. See discussion of transitional rules in Section II.G. of this preamble.

Application to grandfathered health plans. The statute and these interim final regulations relating to the prohibition on lifetime limits apply to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the

prohibition on annual limits, including the special rules regarding restricted annual limits for plan years beginning before January 1, 2014, apply to group health plans and group health insurance coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage.

C. PHS Act Section 2712, Rescissions (26 CFR 54.9815-2712, 29 CFR 2590.715-2712, 45 CFR 147.2712)

PHS Act section 2712 provides rules regarding rescissions⁹ of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard applies to all rescissions, whether in the group or individual insurance market, or self-insured coverage. These rules also apply regardless of any contestability period of the plan or issuer.

These interim final regulations include several clarifications regarding the standards for rescission. First, these interim final regulations clarify that the rules of PHS Act section 2712 apply whether the rescission applies to a single individual or an entire group of individuals. Thus, for example, if an issuer attempted to rescind coverage of an entire employer group based on the actions of an individual within the group, the standards of these interim final regulations would apply. Second, these interim final regulations clarify that the rules of PHS Act section 2712 apply to representations made by the individual or a person seeking coverage on behalf of the individual. Thus, if a plan sponsor seeks coverage from an issuer for an entire employment-based group and makes representations, for example, regarding the prior claims experience of the

⁹ For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission.

group, the standards of these interim final regulations would also apply. Finally, PHS Act section 2712 refers to acts or practices that constitute fraud. These interim final regulations clarify that, to the extent that an omission constitutes fraud, that omission would permit the plan or issuer to rescind coverage under this section. An example in these interim final regulations illustrates the application of the rule to misstatements of fact that are inadvertent.

PHS Act section 2712 adds a new advance notice requirement when coverage is rescinded where still permissible. Specifically, the second sentence in section 2712 provides that coverage may not be cancelled unless prior notice is provided, and then only as permitted under PHS Act sections 2702(c) and 2742(b). Under these interim final regulations, even if prior notice is provided, rescission is only permitted in cases of fraud or an intentional misrepresentation of a material fact as permitted under the cited provisions.¹⁰ While this reference appears redundant, it is consistent with the first sentence.

These interim final regulations provide that a group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 days advance notice to an individual before coverage may be rescinded.¹¹ The notice must be provided regardless of whether the rescission is of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group.

¹⁰ The reference to section 2702(c) appears to be incorrect. After the amendments made by the Affordable Care Act, PHS Act section 2702(c) addresses network requirements for guaranteed availability of coverage. It seems more likely that the intended cross-reference is to new PHS Act section 2703(b), relating to nonrenewal of coverage in the group market, which corresponds to the other cross-reference, in PHS Act section 2742(b), to nonrenewal of coverage in the individual market. Both these provisions contain the fraud and intentional misrepresentation of material fact standard included in the first sentence of section 2712. In order to avoid confusion, these interim final regulations apply the fraud and misrepresentation standard found in sections 2703(b) and 2742(b).

¹¹ Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

These interim final regulations also clarify that other requirements of Federal or State law may apply in connection with a rescission of coverage, including the requirement under PHS Act section 2719(a)(1)(C), which requires a plan or an issuer to allow an enrollee to continue coverage pending the outcome of an appeal of a coverage or claim determination. Regulatory guidance regarding the provisions of PHS Act section 2719 is expected to be issued in the near future.

Application to grandfathered health plans. The rules regarding rescissions and advance notice apply to all grandfathered health plans.

D. PHS Act 2713, Coverage of Preventive Health Services (26 CFR 54.9815-2713, 29 CFR 2590.715-2713, 45 CFR 147.2713)

Section 2713 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations require that a group health plan and a health insurance issuer offering group or individual health insurance coverage provide coverage of certain preventive health care services, and prohibit the imposition of cost-sharing in connection with these services.

The statute and these interim final regulations require coverage of the following:

- Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force.¹²
- Immunizations for routine use in children, adolescents and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved. A recommendation of the the Advisory Committee on Immunization Practices of the

¹² Under PHS Act section 2713(a)(5), United States Preventive Services Task Force recommendations regarding breast cancer screening, mammography, and prevention issued in or around November of 2009 are not to be considered current recommendations on this subject for purposes of PHS Act section 2713(a)(1). Thus, the recommendations regarding breast cancer screening, mammography, and prevention issued by the task force prior to those issued in or around November of 2009 (that is, those issued in 2002) will be considered current until new recommendations in this area are issued by the task force.

Centers for Disease Control and Prevention is considered to be “in effect” after it has been adopted by the Director of the Centers for Disease Control and Prevention.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported Health Resources and Services Administration. Currently, these are the guidelines included as part of the Bright Futures Initiative sponsored by the Health Resources and Services Administration and the American Academy of Pediatrics.
- Health Resources and Services Administration guidelines concerning preventive care and screenings for women (not otherwise addressed by the recommendations of the United States Preventive Services Task Force). No such guidelines currently exist, although the Department of HHS is considering options for developing these guidelines in the near term.

The complete list of recommendations and guidelines that are required to be covered under these provisions can be found at [<http://www.hhs.gov/ociio/regulations/prevention/>]. The statute and these interim final regulations clarify that a plan or issuer may cover preventive services in addition to those required to be covered by PHS Act section 2713.

The statute requires the Departments to establish an interval of not less than one year between when recommendations or guidelines under PHS Act section 2713(a)¹³ are issued, and

¹³ Section 2713(b)(1) refers to an interval between “the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.” While the first part of this statement does not mention guidelines under subsection (a)(4), it would make no sense to treat the services covered under (a)(4) any differently than those in (a)(1), (a)(2), and (a)(3). First, the same sentence refers to “the requirement described in subsection (a),” which would include a requirement under (a)(4). Secondly, the guidelines under (a)(4) are from the same source as those under (a)(3), except with respect to women rather than infants, children and adolescents; and other preventive services involving women are addressed in (a)(1), so there is no plausible policy rationale for treating them differently. Most importantly, if the “interval” under section 2713(b) did not govern when services had to be covered under section 2713(a)(4), it is not clear when such services would have to be covered. It would make no sense to take the position that they had to be covered

the plan year (in the individual market, policy year) for which coverage of the services addressed in such recommendations or guidelines must be in effect. These interim final regulations provide that such coverage must be provided for plan years (in the individual market, policy years) beginning on or after the later of September 23, 2010, or one year after the date the recommendation or guideline is issued. Thus, recommendations and guidelines issued prior to September 23, 2009 must be provided for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

Finally, these interim final regulations make clear that a plan or issuer is not required to provide coverage for any recommendation or guideline after the recommendation or guideline is no longer described in paragraph (a) of this section,¹⁴ but other requirements of Federal or State law may apply in connection with ceasing to provide coverage for any such recommendation or guideline, including the requirement under PHS Act section 2715(d)(4), which requires a plan or an issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

Application to grandfathered health plans. The requirements to cover these preventive health services without any cost-sharing do not apply to grandfathered health plans.

E. PHS Act Section 2714, Continued Eligibility of Children until Age 26 (26 CFR 54.9815-2714, 29 CFR 2590.715-2714, 45 CFR 147.2714)

Section 2714 of the PHS Act, as added by the Affordable Care Act (and amended by the Reconciliation Act), and these interim final regulations provide that a plan or issuer that makes available dependent coverage for children must allow dependent coverage for children until

upon enactment, on March 23, 2010, or to say that because they are not addressed in section 2713(b) they would never have to be covered. Yet, if the interval in section 2713(b) did not apply, it is not clear what other date would govern. These interim final regulations accordingly apply the intervals established therein to services under 2713(a)(4).

¹⁴ For example, if a recommendation of the United States Preventive Services Task Force is downgraded from a rating of A or B to a rating of C or D, or if a recommendation or guideline is superseded by a more current recommendation or guideline.

attainment of 26 years of age. The statute also authorizes the Departments to issue regulations to “define the dependents to which coverage shall be made available” under this rule. These interim final regulations clarify that with respect to children who have not attained age 26, a plan or issuer may not define dependent for purpose of eligibility for coverage other than in terms of the relationship between the child and the participant (in the individual market, the primary subscriber). Examples of factors that cannot limit dependent status include financial dependency, residency with the participant or primary subscriber, student status, employment status, eligibility for other coverage, or any combination of these. These interim final regulations also provide that the terms of the plan or policy for dependent coverage cannot vary based on the age of a child, except for children age 26 or older. Examples illustrate that surcharges for coverage of additional children are not allowed except where the charges apply regardless of the age of the child under age 26 and that the plan cannot vary benefits based on the age of the child under age 26.

Before the enactment of the Affordable Care Act, many group health plans that provided dependent coverage limited the coverage to health coverage excludible from employees’ gross income for income tax purposes. Thus, dependent coverage was limited to employees’ spouses and employees’ children that qualify as dependents for income tax purposes. Consequently, these plans often conditioned dependent coverage, in addition to the age of the child, on student status, residency and financial support or other requirements indicating dependent status. However, with the expansion of dependent coverage required by the Affordable Care Act to children until age 26, whether a child is a dependent is no longer an appropriate factor and may in fact be a proxy for age used to circumvent the new rule. Therefore, these interim final regulations do not allow plans or coverage to use these requirements to deny dependent coverage

to children. Not only are these factors no longer appropriate in determining eligibility for adult children, these factors also may not be used to determine eligibility for dependent coverage for minor children. The statute and these interim final regulations provide that nothing in PHS Act section 2714 requires a plan or issuer to make available coverage for a child of a child receiving dependent coverage.

Application to grandfathered health plans. The statute and these interim final regulations provide that the requirement to make available dependent coverage for children who have not attained age 26 generally applies to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. For plan years beginning before January 1, 2014, these interim final regulations provide that a grandfathered health plan that is a group health plan may exclude an adult child who has not attained age 26 from coverage only if the child is eligible to enroll in an employer-sponsored health plan (as defined in section 5000A(f)(2) of the Code) other than a group health plan of a parent. Thus, in the case of an adult child who is eligible for coverage under the employer-sponsored plans of both parents, neither parent's plan may exclude the adult child from coverage based on the fact that the adult child is eligible to enroll in the other parent's employer-sponsored plan. These interim final regulations also provide an enrollment opportunity for children excluded from coverage because of age before the effective date of the rule.

F. PHS Act Section 2716, Prohibiting Discrimination in Favor of Highly Compensated Individuals (26 CFR 54.9815-2716, 29 CFR 2590.715-2716, 45 CFR 147.2716)

PHS Act section 2716 and these interim final regulations incorporate the nondiscrimination rules of section 105(h) of the Code and apply them to group health plans that

are not self-insured plans. Section 105(h) generally prohibits self-insured medical reimbursement plans from discriminating in favor of highly compensated individuals in eligibility classifications or in benefits. Section 105(b) of the Code generally excludes from an employee's income (otherwise subject to federal income taxation) amounts received as reimbursement of medical care expenses for the employee or the employee's spouse, dependents, or children who have not attained age 27 by the end of the taxable year. If a self-insured medical reimbursement plan does not comply with the requirements of section 105(h), the general exclusion from income (and hence, from federal income taxation) under section 105(b) does not apply with respect to highly compensated individuals. Highly compensated individuals are defined in section 105(h).

PHS Act section 2716 and these interim final regulations incorporate the substantive nondiscrimination requirements of Code section 105(h) but not the tax sanctions. An insured group health plan failing to comply with the nondiscrimination requirements of Code section 105(h) is subject to the sanctions and remedies that generally apply for a plan failing to comply with the requirements of chapter 100 of the Code (generally, an excise tax of \$100 per day per individual for each day the plan does not comply with the requirement), part 7 of ERISA (a civil action to enjoin a noncompliant act or practice or for appropriate equitable relief), or Title XXVII of the PHS Act (civil money penalties of \$100 per day per individual for each day the plan does not comply with the requirement). Thus, if a self-insured plan fails to comply with Code section 105(h), highly compensated individuals lose a tax benefit; if an insured group health plan fails to comply with Code section 105(h), the plan is subject to a civil action to compel it to provide nondiscriminatory benefits and the plan or plan sponsor is subject to an excise tax or civil money penalty of \$100 per day per individual. Rather than restate the rules

under section 105(h) of the Code, these interim final regulations incorporate by reference those rules and applicable regulations.

Application to grandfathered health plans. The rules prohibiting discrimination in favor of highly compensated individuals do not apply to grandfathered health plans (but the rules of Code section 105(h) continue to apply to self-insured plans).

G. Transitional Rules for Individuals Who Reached a Lifetime Limit or a Dependent Eligibility Threshold (26 CFR 54.9815-2800, 29 CFR 2590.715-2800, 45 CFR 147.2800)

Certain new provisions of the PHS Act can affect individuals who previously were covered and lost coverage under a group health plan (in the individual market, policy) or were never eligible for coverage (including individuals denied coverage in the individual market). For example, prior to the applicability date of PHS Act section 2711, an individual may have reached a lifetime limit under a group health plan or health insurance coverage and therefore lost coverage under the plan or coverage. When the provisions of PHS Act section 2711 become applicable to the plan (or coverage), the plan (or coverage) can no longer exclude coverage for the individual by operation of the lifetime limit. Similarly, prior to the applicability date of PHS Act section 2714, an individual who was covered under a group health plan or health insurance coverage as a dependent may have lost eligibility under the plan (or coverage) due to age prior to age 26. Moreover, if, when a parent first became eligible for coverage, a child was under age 26 but older than the age at which the plan (or coverage) stopped covering children, the child would not have become eligible for the plan (or coverage). When the provisions of PHS Act section 2714 become applicable, a plan or issuer can no longer exclude coverage for the individual prior to age 26. Finally, a family member covered through a family policy in the individual market

may be entitled to an opportunity to enroll if the family member is a dependent who previously lost coverage due to age while other family members remained in the coverage.¹⁵

Accordingly, these interim final regulations provide transitional relief for an individual – (1) whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits for any individual; or (2) whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26.

These interim final regulations require a plan or issuer to give such an individual an opportunity to enroll that continues for at least 30 days (including notice of the opportunity to enroll), regardless of whether the plan or coverage offers an open enrollment period and regardless of when any open enrollment period might otherwise occur. This enrollment opportunity must be presented not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010 (which is the applicability date of PHS Act sections 2711 and 2714). Coverage must begin not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, even if it means that the coverage must be retroactive.

Any individual enrolling in group health plan coverage pursuant to this enrollment right must be treated as a special enrollee, as provided under the HIPAA portability rules.¹⁶

Accordingly, the individual must be offered all the benefit packages available to similarly

¹⁵ In the group market, section 9802(a) of the Code, section 702(a) of ERISA, and section 2705 of the PHS Act provide that a plan or issuer cannot impose any rule for eligibility for benefits (including any rule excluding coverage) based on a health factor, including a preexisting condition. These rules were added by HIPAA and generally became applicable for group health plans for plan years beginning on or after July 1, 1997. Similar guidance regarding re-enrollment rights for individuals previously denied coverage due to a health factor was issued by the Departments of the Treasury, Labor, and HHS on December 29, 1997, at 62 FR 67689 and on January 8, 2001 at 66 FR 1378, 1403, 1410, 1418.

¹⁶ See 26 CFR 54.9801-6(d), 29 CFR 701-6(d), 45 CFR 146.117(d).

situated individuals who did not lose coverage due to reaching a lifetime limit or cessation of dependent status. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage due to reaching a lifetime limit or cessation of dependent status.

Examples in these interim final regulations illustrate the application of these transitional rules. One example illustrates that, if a dependent child qualifies for an enrollment opportunity under this section and the parent is not enrolled but otherwise eligible for enrollment, the plan must provide an opportunity to enroll the parent, in addition to the dependent child. Similarly, another example illustrates that, if a plan has more than one benefit package option, a dependent child qualifies for enrollment under this section, and the parent is enrolled in one benefit package option, the plan must provide an opportunity to enroll the dependent in any benefit package option for which the dependent is otherwise eligible (thus allowing the parent to switch benefit package options). Another example illustrates that dependent children covered under a COBRA continuation provision must be given the opportunity to enroll as a dependent of an active employee. In this situation, if the child loses eligibility for coverage due to a qualifying event (including aging out of coverage at age 26), the child has another opportunity to elect COBRA continuation coverage. If the qualifying event is aging out, the COBRA continuation coverage could last 36 months from the loss of eligibility that relates to turning age 26. The final example in this section illustrates that an employee who joined a plan prior to the applicability date of PHS Act section 2714, and has a dependent child who never enrolled because the child was too old under the terms of the plan but has not yet turned 26, has another opportunity to enroll the child under this section even though the child was not previously covered under the plan. If the

parent is no longer eligible for coverage under the plan (for example, if the parent has ceased employment with the plan sponsor), the plan would not be required to enroll the child.

Application to grandfathered health plans. The requirement to give enrollment opportunities to individuals who reached a lifetime limit applies to all grandfathered health plans. The requirement to give enrollment opportunities to individuals who are denied dependent coverage (or who are not eligible for dependent coverage) of a child prior to age 26 applies to all grandfathered health plans that are group health plans or group health insurance coverage, but does not apply to grandfathered health plans that are individual health insurance coverage.

H. Section 1251 of the Affordable Care Act, Preservation of Right to Maintain Existing Coverage (26 CFR 54.9815-2801, 29 CFR 2590.715-2801, 45 CFR 147.2801)

Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and Reconciliation Act section 2301, provides that certain plans existing as of March 23, 2010 (the date of enactment of the Affordable Care Act), are only subject to certain provisions of the Affordable Care Act. The statute and these interim final regulations refer to these plans as grandfathered health plans. The statute and these interim final regulations provide that a group health plan or group or individual health insurance coverage is a grandfathered health plan with respect to individuals enrolled on March 23, 2010 regardless of whether the individual later renews the coverage, subject to rules that disqualify a plan or coverage from the exception for grandfathered health plans if the plan or coverage makes certain changes.

To maintain status as a grandfathered health plan, under these interim final regulations, a plan or issuer must maintain records documenting the plan or policy terms in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan. In addition, the plan or issuer must make such records available for examination. Accordingly, a participant, beneficiary, individual policy

subscriber, State or Federal agency official would be able to inspect such documents to verify grandfathered status.

The statute and these interim final regulations allow family members of individuals who are enrolled in a grandfathered plan to enroll in the plan after March 23, 2010; in such cases, the plan or coverage is also a grandfathered health plan with respect to the family members.

In addition, the statute and these interim final regulations provide that a group health plan that provided coverage on March 23, 2010 generally is also a grandfathered health plan with respect to new employees (whether newly hired or newly enrolled) and their families that enroll in the grandfathered health plan after March 23, 2010; these interim final regulations clarify that in such cases any health insurance coverage provided under the group health plan in which an individual covered under the group health plan was enrolled on March 23, 2010 is also a grandfathered health plan.

The Departments are considering whether the regulations should include measures to prevent an employer from taking advantage of a plan's grandfathered status to enroll large numbers of employees of other employers. In particular, the Departments are considering adopting a final rule under which the enrollment of employees of employers who did not maintain the plan on March 23, 2010 should result in a loss of the plan's grandfathered status, unless the new employers are members of a control group or otherwise share substantial business interests unrelated to the plan. In addition, the Departments are considering adopting a final rule under which inordinate growth of a plan within a single plan year, other than by enrolling new employees of the original sponsoring employers and their families, should affect the plan's grandfathered status. The Departments solicit comments on whether, for example, a plan that grows by the greater of 200 participants or 200 percent within a plan year (not counting new

employees of the original sponsors) should be regarded as so different that it is no longer the same plan for purposes of the grandfather rules of section 1251 of the Affordable Care Act. The Departments also solicit comments on this and other appropriate measures to discourage abuse of grandfathered status.

A special rule for collectively bargained plans provides that, in the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements ratified before March 23, 2010, the coverage is a grandfathered health plan at least until the date on which the last agreement relating to the coverage that was in effect on March 23, 2010 terminates. Thus, before the applicable collective bargaining agreement terminates, any health insurance coverage provided pursuant to the collective bargaining agreement is a grandfathered health plan. After the date on which the last of the collective bargaining agreements terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of paragraph (g) of this section. This determination is made by comparing the terms of the coverage after the date the last collective bargaining agreement terminates with the terms of the coverage that were in effect on March 23, 2010.

A grandfathered health plan generally is not subject to subtitles A and C of title I of the Affordable Care Act, except as specifically provided by the statute and these interim final regulations. The statute and these interim final regulations provide that some provisions of subtitles A and C of title I of the Affordable Care Act continue to apply to all grandfathered health plans and some provisions continue to apply only to grandfathered health plans that are group health plans. These interim final regulations clarify that, to the extent not inconsistent with the provisions that continue to apply to a grandfathered health plan, a grandfathered health

plan must continue to comply with the requirements of the PHS Act, ERISA, and the Code that were applicable prior to the changes enacted by the Affordable Care Act.

The following table summarizes the application of the Affordable Care Act's health coverage reforms that apply to grandfathered plans:

PHS Act Section	Provision	Application to Grandfathered plans	Applies for PY ¹⁷ Beginning on or after
§2701	Fair health insurance premiums	Not applicable	January 1, 2014
§2702	Guaranteed availability of coverage	Not applicable	January 1, 2014
§2703	Guaranteed renewability of coverage	Not applicable	January 1, 2014
§2704	Prohibition of preexisting condition exclusion or other discrimination based on health status	Applicable to grandfathered group health plans and group health insurance coverage. Not applicable to grandfathered individual health insurance coverage.	January 1, 2014 For individuals under age 19, September 23, 2010
§2705	Prohibiting discrimination against individual participants and beneficiaries based on health status	Not applicable	January 1, 2014
§2706	Nondiscrimination in health care	Not applicable	January 1, 2014
§2707	Comprehensive health insurance coverage (applicable to issuers in the individual and small group markets)	Not applicable	January 1, 2014
§2708	Prohibition on excessive waiting periods	Applicable	January 1, 2014
§2709	Coverage for individuals participating in approved clinical trials	Not applicable	January 1, 2014
§2711	No lifetime or annual limits	Lifetime limits: Applicable Annual limits: Applicable to grandfathered group health plans and group health insurance coverage; not applicable to grandfathered individual health insurance coverage. ¹⁸	September 23, 2010
§2712	Prohibition on Rescissions	Applicable	September 23, 2010
§2713	Coverage of preventive health	Not applicable	September 23, 2010

¹⁷ As used in this chart, PY refers to plan year (in the individual market, policy year).

¹⁸ Restricted annual limits may be imposed for plan or policy years beginning before January 1, 2014 in amounts specified in these interim final regulations.

§2714	Extension of dependent coverage	Applicable ¹⁹	September 23, 2010
§2715	Development and utilization of uniform explanation of coverage documents and standardized definitions	Applicable	September 23, 2010
§2715A	Provisions of additional information	Not applicable	September 23, 2010
§2716	Prohibition of discrimination based on salary (not applicable to self-insured plans)	Not applicable	September 23, 2010
§2717	Ensuring quality of care	Not applicable	September 23, 2010
§2718	Bringing down cost of health care coverage (for insured coverage)	Applicable to insured grandfathered plans	September 23, 2010
§2719	Appeals process	Not applicable	September 23, 2010
§2719A	Patient Protections	Not applicable	September 23, 2010

These interim final regulations include rules for determining when changes to the terms of the grandfathered health plan cause the plan or coverage to cease to be a grandfathered health plan. These rules specify certain changes that cause a plan to lose status as a grandfathered health plan, and also changes that will not cause a plan to lose status as a grandfathered health plan.

Specifically, paragraph (g)(1) of this section of these interim final regulations provides that a grandfathered health plan will lose grandfather status if there is an increase, since March 23, 2010, in a fixed-amount cost-sharing requirement that is greater than 15 percent plus the increase in the overall medical care component of the Consumer Price Index for All Urban Consumers (unadjusted) published by the Department of Labor (CPI) since March 2010. Fixed-amount cost-sharing includes, for example, a \$500 deductible, a \$30 copayment, or a \$2,500 out-of-pocket limit. The Departments acknowledge that medical inflation, as determined by the

¹⁹ For grandfathered group health plans and group health insurance issuers, for plan years beginning before January 1, 2014, PHS Act section 2714 is applicable in the case of an adult child only if the adult child is not eligible for other employer sponsored health plans coverage (as described in these interim final regulations). These interim final regulations clarify that, in the case of an adult child who is eligible for coverage under the employer-sponsored plans of both parents, neither parent's plan may exclude the adult child from coverage based on the fact that the adult child is eligible to enroll in the other parent's employer-sponsored plan.

overall medical component of CPI, does not parallel medical inflation for any particular item or service. Accordingly, to smooth out some of these differences, these interim final regulations do not automatically cause grandfathered health plans to lose their grandfathered status if a plan or issuer raises an individual copayment or other fixed-amount cost-sharing by more than the overall rate of medical inflation. Instead, these interim final regulations provide that an increase in a deductible, copayment, or other fixed-amount cost-sharing will cause a plan to lose grandfathered status if the increase exceeds 15 percent plus the rate of medical inflation (as determined using the formula set forth in the regulations). Paragraph (g)(2) of this section of these interim final regulations provides that an increase that does not exceed this amount does not cause a grandfathered health plan to lose its grandfathered status.

In addition, paragraph (g)(1) of this section of these interim final regulations provides that an increase in a percentage cost-sharing requirement (such as increasing an individual's 20 percent coinsurance requirement to 25 percent) will cause a plan to lose grandfathered status. These cost-sharing arrangements already take into account, to some degree, medical inflation. That is, to the extent the cost of a medical item or service increases, an individual may be required to pay more for it under a percentage cost-sharing requirement. Accordingly, percentage cost-sharing requirements are treated differently than fixed-amount cost-sharing under the grandfather provisions of these interim final regulations.

These interim final regulations also provide that the elimination of all or substantially all benefits to diagnose or treat a particular condition will cause a plan to lose grandfathering, regardless of whether the change is considered a substantial change overall under the plan. Therefore, for example, if a plan eliminates all benefits for cystic fibrosis, which affects relatively few individuals covered under the plan, the plan will cease to be a grandfathered health

plan, even if that change in benefit design is not considered a substantial change under paragraph (g)(3) of this section of these interim final regulations.

Paragraph (g)(2) of this section of these interim final regulations sets forth changes that do not affect grandfathered status. Specifically, the following changes do not affect grandfathered status: changes in the premiums charged by an issuer for coverage; changes in the amount that an employer or employee organization contributes toward coverage; changes to comply with applicable Federal or State legal requirements; changes to voluntarily comply with provisions of the Affordable Care Act that do not apply to grandfathered health plans; replacing a lifetime limit with an annual limit as permitted by 26 CFR 54.9815-2711, 29 CFR 2590.715-2711, or 45 CFR 147.2711 (discussed earlier in this preamble); or any decrease in cost-sharing for the individual or an increase in covered benefits.

For other changes, paragraph (g)(3) of this section of these interim final regulations provides a general standard for determining whether the plan or coverage is the same plan or coverage in which an individual was enrolled on March 23, 2010. Specifically, paragraph (g)(3) provides that a change not described in paragraph (g)(1) or (g)(2) of this section does not cause a plan (in the individual market, policy) to lose grandfathered status, unless one or more of such changes, in the aggregate and determined cumulatively since March 23, 2010, result in the coverage under the plan (or policy) being substantially different than the coverage that was provided on March 23, 2010. Whether or not there has been a substantial change is a facts and circumstances determination.

Examples illustrate the operation of the rules for grandfathered health plans. The Departments request comments regarding the rules for grandfather health plans[, including the impact of the provisions on plans and issuers that made changes to plan terms after March 23,

2010 but prior to issuance of these interim final regulations as well as the impact on plans that made changes to plan terms after March 23, 2010 pursuant to a contract entered into prior to that date].

I. Individual Market and Non-Federal Governmental Plan Reforms

1. References to the Public Health Service Act

Conforming changes to references to sections of Title XXVII of the PHS Act are made throughout Parts 144 and 146 to reflect the renumbering of certain sections by the Affordable Care Act.

2. Definitions (45 CFR 144.103)

These interim final regulations define “policy year” as the 12-month period that is designated in the policy documents of individual health insurance coverage. If the policy document does not designate a policy year (or no such document exists), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year. The Affordable Care Act uses the term “plan year” in referring to the period of coverage in both the individual and group health insurance markets. The term “plan year,” however, is generally recognized as having only relevance in the group health insurance market. Accordingly, these interim final regulations substitute the term “policy year” for “plan year” in defining the period of coverage in the individual health insurance market.

These interim final regulations revise the definition of “preexisting condition exclusion” to clarify that the denial of an application for coverage because of a preexisting condition in the individual health insurance market is a preexisting condition exclusion. This definition at 45 CFR 144.103 is cross-referenced in both 45 CFR 146.111(a)(1) and 45 CFR 147.2704, and it

applies in both the group and individual health insurance markets, and also to entities that provide coverage to Federally eligible individuals.

3. Treatment of Non-Federal Governmental Plans (45 CFR 146.180)

The Affordable Care Act made numerous changes to Title XXVII of the PHS Act, including to section 2721(b)(2), which permitted the sponsor of a self-funded non-Federal governmental plan, as defined in 45 CFR 144.103, to elect to exempt the plan from certain requirements of Title XXVII of the PHS Act. This is referred to herein as the “opt-out provision.” Section 1001(4) of the Affordable Care Act re-designated section 2721 as section 2735. Section 1562(b)(12) of the Affordable Care Act amended section 1001(4) by re-designating section 2735(b)(2) as section 2722(a)(2).

Additionally, section 1562(a)(2) of the Affordable Care Act further amended the opt-out provision in §2722 by adding a new subparagraph (a)(2)(E), which prohibits a sponsor of a self-funded non-Federal governmental plan from electing to exempt the plan from the Subparts I and II in Part A of the revised Title XXVII. Subpart I (“General Reform”) contains the provisions of the original Subpart 1 of Part A of title XXVII of the PHS Act. The requirements in the original Subpart 1 included limitations on preexisting condition exclusion periods, special enrollment periods and prohibitions against discriminating against individual participants and beneficiaries based on health status. Because of the prohibition in PHS Act section 2722(a)(2)(E), self-funded non-Federal governmental plans can no longer elect to be exempted from these provisions in Subpart I starting with plan years beginning on or after September 23, 2010.

Section 1001(2) of the Affordable Care Act redesignated sections 2704 through 2707 (which respectively set forth the provisions of the Newborns’ and Mothers’ Health Protection Act of 1996, the Mental Health Parity Act of 1996 (as amended by the Mental Health Parity and

Addiction Equity Act (2008)), the Women's Health and Cancer Rights Act of 1998, and Michelle's Law (2008)) as sections 2725 through 2728, respectively, which are contained in a revised Subpart 2, "Exclusion of Plans; Enforcement; Preemption." A sponsor of a self-funded non-Federal governmental plan may continue to elect to exempt its plan from the requirements of Subpart 2 (which is separate from Subpart II) of Part A of Title XXVII since the prohibition in section 2722(a)(2)(E) does not reference Subpart 2.

Section 1004 of the Affordable Care Act provides, in pertinent part, that the amendments made by section 1001 are "effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act[.]" The Affordable Care Act was enacted on March 23, 2010. Therefore, section 1001, as amended by section 1562(a) and (b)(12), is effective for group health plan years beginning on or after September 23, 2010. The Affordable Care Act makes no exception for plan years beginning on or after September 23, 2010 that are governed by a previously ratified collective bargaining agreement under which the plan sponsor has elected to exempt the self-funded plan from one or more requirements of Subpart 1. The grandfathering provision in section 1251(d) of the Affordable Care Act only applies to insured collectively bargained plans. Accordingly, without regard to a collective bargaining agreement, a sponsor of a self-funded non-Federal governmental plan that commences a new plan year on or after September 23, 2010 can no longer elect to exempt the plan from requirements of Subpart 1. An example in these interim final regulations illustrates this.

Section 146.180 is being revised to reflect changes made by the Affordable Care Act, to add conforming changes and to make certain additional changes unrelated to the Affordable Care Act, such as updating the address to which an opt-out election should be submitted, updating an example to reflect more recent dates, and removing outdated text.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of subtitle K of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act 2701 through 2728 and the incorporation of them into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

These rules are being adopted on an interim final basis because the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process is completed. The statutory requirements implemented in these interim final regulations were enacted on March 23, 2010, and apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Yet, the requirements in these regulations require significant lead time in order to implement.

For example, in the case of the requirement under PHS Act section 2714 to allow dependent children to enroll in a group health plan until they are 26, these interim final regulations require that an enrollment period be provided for no later than the first day this requirement takes effect. Preparations presumably would have to be made to put such an enrollment process in place. In the case of preventive health services that must be provided under section PHS Act section 2713, if the recommendation or guideline requiring coverage of the service was issued before September 23, 2009, group health plans and health insurance issuers have to be prepared to provide coverage of the preventive services by as early as the first plan or policy year beginning on or after September 23, 2010. With respect to all the changes that would be required to be made under these interim final regulations, whether adding coverage of children with a preexisting condition under PHS Act section 2704, or eliminating lifetime limits under PHS Act section 2711, group health plans and health insurance issuers have to be able to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits, and these premiums and plan or policy changes would have to receive necessary approvals in advance of the plan or policy year in question.

For the foregoing reasons, the Departments have determined that it is essential to provide certainty about what will be required of group health plans and health insurance issuers under the statutory requirements implemented in these final regulations as far in advance of September 23, 2010 as possible. This makes it impracticable to engage in full notice and comment rulemaking before putting regulations into effect, and in the public interest to do so through interim final regulations under which the public will have an opportunity for comment, but that opportunity will not delay putting rules in effect (a delay that could possibly last past September 23, 2010).

Having a binding rule in effect is critical to ensuring that individuals entitled to the new protections being implemented have these protections uniformly applied. Even if a notice of proposed rulemaking were issued, it would not be binding, and different group health plans or health insurance issuers could interpret the statutory language in different ways. It therefore is in the public interest that these interim final regulations be in effect and apply when the statutory protections being implemented apply.

IV. Economic Impact and Paperwork Burden

[insert new RIA]

V. Statutory Authority

The Department of the Treasury temporary and final regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104-191, 110 Stat. 1936; sec. 401(b), Public Law 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110-343, 122 Stat. 3765; Public Law 110-460, 122 Stat. 5123; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

From: [Turner, Amy - EBSA](#)
To: [Mayhew, James A. \(CMS/CPC\)](#); [Kosin, Donald \(HHS/OGC\)](#); [Corrigan, Dara \(HHS/OHR\)](#); [russell.e.weinheimer@irscounsel.treas.gov](#); [Kevin.Knopf@do.treas.gov](#); [Karen.B.Levin@irscounsel.treas.gov](#); [Alan.Tawshunsky@irscounsel.treas.gov](#); [George.Bostick@do.treas.gov](#); [helen.morrison@do.treas.gov](#)
Subject: Fw: Comment Letter
Date: Friday, May 28, 2010 11:52:57 AM
Attachments: [05262010160348836.pdf](#)
[image803eac.gif@5278f116.7c144875](#)
Importance: High

Fyi

Sent via Blackberry

From: Tinnes, Christy (CAT@groom.com) <CTinnes@groom.com>
To: Turner, Amy - EBSA
Sent: Fri May 28 11:23:55 2010
Subject: Comment Letter

Hi Amy -

We have a client who is trying to send in comments related to annual limit guidance. I know there is no formal RFI, but we keep hearing that now is the time to submit comments. He's not sure where to file (other than sending to Secretary Sebelius). I'm attaching here (as you are my "channel with the DOL"), but if there is somewhere else I should send, please let me know. I'm simply forwarding along - we didn't draft these.

I talked to Janet Walters this week about DOL Speaks - that sounds fun. And it's at National Harbor, which is neat. Since it's a Monday, I may bring my boat down for the weekend.

Good luck with all these regs - I know this must be a ton of work (although I'm personally kind of happy nothing came out before Memorial Day!).

Christy

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From: Chris Caveness [<mailto:caveness@hwbs.com>]
Sent: Wednesday, May 26, 2010 4:22 PM
To: St. Martin, Andree (ams@groom.com); Tinnes, Christy (CAT@groom.com)
Cc: Jeff Webb
Subject: Secretary Sebelius Letter
Importance: High

Hello Andre & Christy.

I understand we have a small window to get comments to Secretary Sebelius and HHS about the annual limits clarification in the Patient Protection & Affordable Care Act.

Please use your channels with the DOL to have the attached letter get into the hands of the decision makers finalizing the rules on annual benefits limits and the transition to 2014.

Thanks!!!!

Chris



Chris Caveness, President
P.O. Box 21109
Roanoke, VA 24018
T. 800.283.4927
F. 540.725.3738
<http://www.hwbs.com>

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May 26, 2010

The Honorable Kathleen Sebelius
Secretary, Department of Health & Human Services
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Severely Disabled Losing Health Insurance in Patient Protection & Affordable Act Transition to 2014

Dear Secretary Sebelius,

The Patient Protection & Affordable Care Act, as an unintended consequence, will cause several hundred thousand citizens, with severe disabilities, to lose their employer sponsored and paid for insurance coverage until the availability of subsidies and other coverages becomes available in 2014.

I encourage you to support transitional regulatory guidance that would prevent, until 2014, the disruption of employer sponsored and paid for group health insurance provided through self insured and fully insured limited benefit plans.

Severely disabled employees are employed by non profit agencies (NPA's) participating in the federally funded Javitz Wagner O'day or AbilityOne program which provides employment opportunities for people who are blind or have other severe disabilities. Some NPA's also provide employment opportunities through state sponsored programs.

These NPA's can not afford to provide major medical insurance coverage to large groups of severely disabled employees on their payroll until all facets of the Patient Protection & Affordable Care Act is in full swing in 2014. Their limited benefit programs would be terminated because other options are not available yet.

Please take proactive steps to protect the severely disabled and *ensure limited benefit programs established on a self insured and fully insured basis* are exempted from the new annual dollar limit rules by temporarily excluding grandfathered group limited medical benefit plans from the annual benefit limit provisions until 2014. This measure will protect insured persons with severe disabilities receiving coverage now on a guaranteed issue basis covering preexisting conditions as well as other citizens being provided limited benefit plans by their employers.

By preserving these self insured and fully insured limited benefit coverage plans, you will enable NPA's to transition to traditional coverage as new options open in 2014 as a result of the Act.

Sincerely yours,

A handwritten signature in black ink that reads "Chris Caveness". The signature is fluid and cursive, with a large initial "C" and a stylized "Caveness" following.

Chris Caveness
President

From: [Drobac, Krista \(HHS/OCIIO\)](#)
To: [Mayhew, James A. \(CMS/CPC\)](#); [Larsen, Steven \(HHS/OCIIO\)](#)
Subject: FW: 1:00pm Weds - Annual Limits meeting
Date: Tuesday, May 18, 2010 5:01:10 PM
Attachments: [Guardsmark Proposal \(HHS\) 050410.doc](#)

Looks like the meeting I'll be attending tomorrow is also on the annual limits issue. Attached is a proposal from the company.

From: Fitzgerald, Erin (HHS/ASL)
Sent: Tuesday, May 18, 2010 2:49 PM
To: Drobac, Krista (HHS/OCIIO)
Subject: RE: 1:00pm Weds - Annual Limits meeting

We are all set to meet with Guardmark (and Schumer and Wyden' offices) tomorrow at 1:00pm. We'll be meeting in Wyden's office - Dirksen 223. I have a car for us leaving at 12:45pm from 1B.

Also, I believe I sent this over before, but attached is the proposal Guardsmark wrote up on how they want HHS to define restricted annual limits prior to 2014.

Thanks a million (and awesome haircut),
Erin

Erin Fitzgerald
Office of the Assistant Secretary for Legislation
U.S. Department of Health and Human Services

**Proposal of Guardsmark LLC
Regarding Regulations Implementing New Section 2711
Of the Public Health Service Act Regarding Annual Benefit Limits
April 30, 2010**

Summary: Guardsmark provides no-premium health insurance to its private-security officer employees, and they participate at a rate of 76%. In order to make this generous benefit economically rational, however, the company imposes certain annual benefit limits. While the company is planning now to end the annual limits by 2014, it needs regulatory flexibility on its annual limits policy between today and 2014 in order to continue offering a no-premium benefit that results in high employee participation rates. The following is a regulatory justification and proposal to achieve this result.

1. Background on Company Health Plan. Guardsmark employs approximately 17,000 people nationwide in the private security industry. While Guardsmark has higher salaries and much lower turnover than its industry competitors, a significant portion of its employees are at the lower end of the economic ladder. Guardsmark has offered all full-time employees a no-premium health insurance plan since 2004, in order to maximize employee participation in our health-care plan, and the current employee participation rate is 76% as a result. We are confident that, if a premium were imposed, employee participation would decrease significantly.

In order to make this no-premium policy economically viable for the company, however, Guardsmark has imposed an annual benefit limit of \$25,000. With respect to 99% of plan members, the annual limit is never reached. While “catastrophic” illnesses do arise, the company offers supplemental coverage for many of such conditions, and some employees choose this option. Raising the annual limit immediately for all employees, however, or removing it entirely, would dramatically raise the cost to the company of its health insurance plan, the company would be forced to impose an employee premium, and reduced employee participation is almost certain. Guardsmark wishes to avoid this result.

2. New Annual Limits. New Section 2711(a) of the Public Health Service Act clarifies that no annual limits will be permitted as of the 2014 plan year, requires the package of “essential health benefits” to be offered by any employer offering health insurance before that date, and directs the Secretary of HHS to draft regulations defining the manner in which an annual limit may be imposed prior to 2014. There are two statutory parameters that the Secretary must follow: (i) no annual limit may eliminate a health benefit deemed “essential,” although a reduction in the scope of any such benefit is permitted; and (ii) the “Secretary shall ensure that access to needed services is made available with a minimal impact on premiums.”

3. Need for Regulatory Relief. Guardsmark respectfully submits that it falls precisely into the category of companies that this Section 2711 addresses. As described by the economic analysis above, failure by HHS to provide Guardsmark and similarly situated

companies with flexibility on annual limits prior to 2014 will result in regrettable but necessary premium increases, and therefore an almost certain decreased participation by employees in existing group health care plans. In order to avoid this result, regulatory flexibility on annual limits during the current transition period is critical.

4. Proposed Regulatory Language. Guardsmark proposes that the following concept or language be included in the upcoming HHS regulation implementing the annual benefit limits transition period:

“Between the date of enactment of Section 2711(a) of the Public Health Service Act (as amended by the Patient Protection and Affordable Health Care Act of 2010) and January 1, 2014, an employer providing health care insurance to its employees prior to December 31, 2009, may continue to impose any annual benefit limits it had in effect on such date, provided that:

“(i) as of the effective date of this rule, the company offers coverage available under its health insurance plan for all “essential health benefits” as defined in Section 1302(b) of the Patient Protection and Affordable Health Care Act, subject to any annual benefit limits permitted by this rule, and

“(ii) it does not increase the level of premium charged to its employees participating in such plan because of the new annual limit restrictions.

Nothing in this rule shall be construed to prevent an employer described in this section from imposing or increasing a premium to its employees for health care insurance based on the elimination of other benefit limits pursuant to the Patient Protection and Affordable Health Care Act of 2010.”

From: [Mayhew, James A. \(CMS/CPC\)](#)
To: [Drobac, Krista \(HHS/OCHIO\)](#)
Subject: Re: Hill Q - Annual Limits
Date: Friday, May 14, 2010 7:16:56 PM

We can't elaborate at this point what "restricted" means- still up for discussion. The retracted annual limit provision does not apply to grandfathered individual plans. Finally, the reconciliation bill did not move up the date to 2010.

Jim Mayhew
Director, Division of Private Health Insurance
Centers for Medicare & Medicaid Services

Sent from my Blackberry Handheld Device

From: Drobac, Krista (HHS/OCHIO)
To: Fitzgerald, Erin (HHS/ASL)
Cc: Taylor, Bridgett (HHS/ASL); Kidwell, Lauren (HHS/ASL); Engel, Elizabeth (HHS/ASL); Mayhew, James A. (CMS/CPC)
Sent: Fri May 14 18:29:50 2010
Subject: Re: Hill Q - Annual Limits

Jim: can you answer these follow up questions? Thanks.

From: Fitzgerald, Erin (HHS/ASL)
To: Drobac, Krista (HHS/OCHIO)
Cc: Taylor, Bridgett (HHS/ASL); Kidwell, Lauren (HHS/ASL); Engel, Elizabeth (HHS/ASL)
Sent: Fri May 14 18:27:41 2010
Subject: RE: Hill Q - Annual Limits

Hey Krista – sorry to bug again. Just wanted to check in on these two follow-up q's. We're getting bugged by Hill offices on these issues. Thanks!

From: Fitzgerald, Erin (HHS/ASL)
Sent: Wednesday, May 12, 2010 6:44 PM
To: Drobac, Krista (HHS/OCHIO)
Cc: Engel, Elizabeth (HHS/ASL); Taylor, Bridgett (HHS/ASL); Kidwell, Lauren (HHS/ASL)
Subject: RE: Hill Q - Annual Limits

Hey there – quick follow-up questions to your email below.

1) In the sentence about annual limits you say that they will be permissible on a "restricted" basis for group health plans – are you able to elaborate what "restricted" means? Is it the same as for the individual plans in existence on March 23, 2010 and described in the last sentence?

2) Also, while the Senate bill allowed group plans to maintain annual limits until 2014, did the reconciliation bill move it up to 2010. Is that wrong?

Thanks!
Erin

From: Drobac, Krista (HHS/OCHIO)
Sent: Thursday, May 06, 2010 9:16 AM

To: Fitzgerald, Erin (HHS/ASL)
Cc: Engel, Elizabeth (HHS/ASL); Taylor, Bridgett (HHS/ASL); Kidwell, Lauren (HHS/ASL)
Subject: RE: Hill Q - Annual Limits

We are hearing a lot about this issue. The brokers are ginning it up. Given that the reg is still under development, here is what I think we can say:

The statute only prohibits lifetime limits for plan or policy year beginning on or after September 23, 2010. Annual limits will be permissible on a restricted basis for group health plans and individual health insurance plans until January 1, 2014. The regulations will discuss in some detail the restrictions on annual limits. For individual health insurance plans that were in existence on March 23, 2010, the existing annual limits will be permitted to remain the same for as long as the individual keeps the policy and as long as there is no substantial change to the policy.

From: Fitzgerald, Erin (HHS/ASL)
Sent: Wednesday, May 05, 2010 11:16 PM
To: Drobac, Krista (HHS/OCIIO)
Cc: Engel, Elizabeth (HHS/ASL); Taylor, Bridgett (HHS/ASL); Kidwell, Lauren (HHS/ASL)
Subject: Hill Q - Annual Limits

Hey Krista - offices are hearing a lot of concerns from businesses in their state as to how the "no lifetime/ annual limits" provision will affect the businesses' premiums and/or the insurance options they have. Here's one specific question we have. Can you help answer?

Thanks,
Erin

Background: Rep. Larsen and Senator Cardin are concerned that the prohibition on annual benefit limits will force out group limited benefit plans. These cheaper plans offer very limited benefits, and Larsen/Cardin agree that we don't want people in plans like that in the long term. However, 1.5 million people currently have limited benefit plans, and they are concerned about what will happen to these 1.5 million people in the gap between when this provision takes effect later this year, and when the exchanges are up and running in 2014. Cardin's folks are also worried about the insurers offering these plans will go out of business. They are concerned that because they have mostly healthy people that they won't be able to meet the MLR (duh), they want to know how we will handle this.

Q: How does HHS plan to address the possibility that the prohibition of annual benefit limits will force out group limited benefit plans? Obviously we can't pre-judge the regs and if any specific groups of people will be addressed specifically, but is there any info we can share?

.

From: [Mayhew, James A. \(CMS/CPC\)](#)
To: [Larsen, Steven \(HHS/OCIIO\)](#)
Subject: FW: Reg Text 4.27.10 1pm
Date: Wednesday, May 12, 2010 10:06:00 PM
Attachments: [Reg Text 4.27.10 1pm.doc](#)

Here is the bundled reg text before the WH requested that it be broken out.

>-----Original Message-----

>From: Baum, Beth - EBSA [<mailto:baum.beth@dol.gov>]

>Sent: Tuesday, April 27, 2010 2:48 PM

>To: Baum, Beth - EBSA; Benson, Susanna - SOL; Butikofer, James - EBSA;

>Corrigan, Dara (HHS/ASPE); Cosby, Chris - EBSA;

>Helen.Morrison@do.treas.gov; Karen Levin - HOME; Knopf Kevin - OTP;

>Kosin, Donald (HHS/OGC); Levin Karen; Mayhew, James A. (CMS/CPC);

>Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV; Schumacher, Elizabeth - EBSA;

>Tawshunsky Alan; Taylor, William - SOL; Turner, Amy - EBSA

>Subject: Reg Text 4.27.10 1pm

>

> <<Reg Text 4.27.10 1pm.doc>> The edits we made to the reg text this
>afternoon.

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

**PART 2590—RULES AND REGULATIONS FOR HEALTH INSURANCE
PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS**

1. The authority citation for Part 2590 is revised to read as follows:

Authority:

Subpart B—Other Requirements

2. Section 2590.701-2 is amended by revising the definition of preexisting condition exclusion to read as follows:

§ 2590.701-2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or

group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

3. Section 2590.701-3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 2590.701-2 of this Part.

* * * * *

4. Section 2590.715 is added to Subpart C to read as follows:

§ 2590.715-2704 Prohibition of preexisting condition exclusions.

(a) In general. (1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701-2 of this Part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage ~~because due to the fact that~~ a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition. (The denial of an application for coverage based on a preexisting condition exclusion also violates PHS Act section 2702 (guaranteed availability of coverage) and PHS Act section 2705 (prohibition against discrimination based on health status) for policy years beginning on or after January 1, 2014.)

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child into the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma beginning on January 1, 2011, regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13 year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13 year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13 year-old child.

§ 2590.715-2711 No lifetime or annual limits.

(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may establish, for any individual, an annual limit on the dollar

amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining ~~whether~~ ~~if~~ an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(e) Enrollment rights for individuals previously subject to lifetime limits. See § 2590.715-2800 of this Part for rules requiring that an enrollment opportunity be given to certain individuals who have reached a lifetime limit on the dollar value of all benefits before the date that the requirements of this section apply.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2712 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage

under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission.

(3) The rules of this paragraph (a) are illustrated by the following example:

Example. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A was treated for acne six years ago. A is later diagnosed

with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's prior treatment for acne, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example, the plan cannot rescind A's coverage because A's failure to disclose the prior treatment for acne was not fraudulent or an intentional misrepresentation of material fact.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage, including the requirement under PHS Act section 2719(a)(1)(C), which requires a plan or an issuer to allow an enrollee to continue coverage pending the outcome of an appeal of a coverage or claim determination.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2713 Coverage of preventive health services.

(a) In general—(1) Beginning at the time described in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements with respect to those items or services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

(2) Nothing in this paragraph (a) prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines.

(b) Timing—(1) In general. A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that

begin on or after the later of September 23, 2010, or one year after the date the recommendation or guideline is issued.

(2) Changes in recommendations or guidelines. A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services-recommendation or guideline, including PHS Act section 2715(d)(4), which requires a plan or an issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) Recommendations not current. For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2714 Eligibility of children until at least age 26.

(a) In general. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, that makes available dependent coverage offer children must allow such coverage offer children until attainment of 26 years of age.

(b) Restrictions on plan definition of dependent. With respect to children who have not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage ~~for of~~ ~~of~~ children other than in terms of a relationship between a child and the participant (in the individual market, the primary subscriber). Thus, for example, a plan or issuer may not deny or restrict coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency ~~(upon the participant or primary subscriber, or any other person)~~, residency with the participant (in the individual market, with the primary subscriber) ~~or with any other residency~~ ~~person~~, student status, employment, or any combination of those factors. In addition, a plan or issuer may not deny or restrict coverage ~~for of~~ a child based on eligibility for other coverage, except that paragraph (g) of this section provides a special rule for plan years beginning before January 1, 2014 for grandfathered health plans that are group health plans. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may mandate coverage ~~for of~~ certain children.)

Comment [K1]: Should we add this to make clear that financial dependency on a participant is not a "relationship" between child and participant?

(c) Coverage of grandchildren not required. Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) Uniformity irrespective of age. The terms of the plan or health insurance coverage providing dependent coverage ~~offor~~ children cannot vary based on age (except for children who are age 26 or older).

(e) Examples. The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) Conclusion. In this Example 1, the plan violates the requirements of paragraph (d) of this section because the plan varies the terms for dependent coverage ~~for~~ ~~of~~ children based on age.

Example 2. (i) Facts. A group health plan offers a choice among the following tiers of health coverage: self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage ~~for~~ ~~to~~ children who have not attained age 26.

(ii) Conclusion. In this Example 2, the plan does not violate the requirement of paragraph (d) of this section that the terms of coverage for dependent children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any dependent child.

Example 3. (i) Facts. A group health plan offers two benefit packages -- an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) Conclusion. In this Example 3, the plan violates the requirements of paragraph (d) of this section because the plan varies the terms for dependent coverage ~~for~~ ~~of~~ children based on age.

(f) Enrollment rights for individuals who previously lost dependent status. See § 2590.715-2800 of this Part for rules requiring that an enrollment opportunity be given to certain children under age 26 who are not granted coverage before the date ~~on which that~~ the requirements of this section apply.

(g) Special rule for grandfathered group health plans. For plan years beginning before January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act may exclude an adult child who has not attained age 26 from coverage only if the adult child is eligible to

enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a group health plan of a parent.

(h) Applicability date. The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2716 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code that apply to self-insured medical reimbursement plans (prohibiting discrimination in favor of highly compensated individuals as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-insured plan) under this section as if the group health plan were a self-insured medical reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2800 Transitional rules for individuals whose coverage ended by reason of due to reaching a lifetime limit or a dependent eligibility threshold.

(a) Applicability. The relief provided in the transitional rules of this section applies with respect to any individual who becomes eligible for coverage under a group health plan or group or individual health insurance coverage upon the effective date of a provision of subtitle A or subtitle C of title I of the Patient Protection and Affordable Care Act or the regulations thereunder and:

(1) Whose coverage under a group health plan or group or individual health insurance coverage ended by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, ~~is no longer permissible~~ under § 2590.715-2711 of this Part, is no longer permissible); or

(2) Whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or group or individual health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage

of children ended before the attainment of age 26 (which, ~~is no longer permissible~~ under § 2590.715-2714 of this Part, ~~is no longer permissible~~).

(b) Opportunity to enroll required—(1) ~~For an individual described in paragraph (a) of this section, if~~ a group health plan, or ~~the~~ group or individual health insurance coverage, in which ~~an individual described in paragraph (a) of this section the individual~~ is eligible to enroll is the plan or coverage in which the individual's coverage ended for the reasons described in paragraphs (a)(1) or (a)(2) of this section, and if the plan, or the issuer of such coverage, is subject to the requirements of § 2590.715-2711 or § 2590.715-2714 of this Part, the plan ~~or and the~~ issuer ~~is are~~ required to give the individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This opportunity must be ~~provided beginning presented~~ not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(2) The written notice must include a statement that individuals who lost coverage by reason of reaching a lifetime limit, or whose coverage ended, or who ~~was were~~ denied coverage (or were not eligible for coverage) because the availability of dependent coverage ~~for children ended by reason of ceasing to be a dependent~~ before attainment of age 26, as applicable, ~~are~~ eligible to enroll in the plan or coverage. The written notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. In the case of a group health plan providing benefits through health insurance coverage, a notice provided by the plan or the issuer satisfying the requirements of this paragraph (b) also satisfies these requirements with respect to the issuer or the plan.

(3) In the case of an individual who enrolls under this paragraph (b), coverage must take effect not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(c) Treatment of enrollees in a group health plan. For purposes of this Part, any individual enrolling in a group health plan pursuant to paragraph (b) of this section must be treated as if the individual were a special enrollee, as provided under the rules of § 2590.701-6(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit or cessation of dependent status. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit or cessation of dependent status.

(d) Examples. The rules of this section are illustrated by the following examples:

Example 1. (i) Facts. Employer X maintains a group health plan with a calendar year plan year. For the 2010 plan year, the group health plan imposes a \$1 million lifetime limit. Individual A is an employee of X and a participant in X's group health plan. On April 15, 2010, A incurs claims under the group health plan that, together with all previous claims, exceed the lifetime limit. On November 1, 2010, X's group health plan provides written notice to A that individuals who lost coverage by reason of reaching a lifetime limit are eligible to enroll in the plan or coverage during the plan's open season for the 2011 plan year, which runs from November 15, 2010 to December 15, 2010. Enrollment will become effective on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this section that it present an enrollment opportunity to A.

Example 2. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. For the 2010 plan year, the group health plan allows children of employees to be covered under the plan until age 19, or until age 23 for children who are full-time students. Individual B, an employee of Y, and Individual C, B's child and a full-time student, were enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, C turns 23 years old and loses dependent coverage under Y's plan. On or before January 1, 2011, Y's group health plan gives B written notice that individuals who lost coverage by reason of ceasing to be a dependent before attainment of age 26 are eligible to enroll in the plan or coverage, and that individuals may request enrollment for such dependents through February 14, with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 2, the plan has complied with the requirements of this section that it present an enrollment opportunity to C.

Example 3. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan allows children of employees to be covered under the plan until age 22. Individual D, an employee of Z, and Individual E, D's child, are enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E turns 22 years old and ceases to be eligible as a dependent under Z's plan and loses coverage. D drops coverage but remains an employee of Z before October 1, 2010.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 4. (i) Facts. Same facts as Example 3, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 4, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 5. (i) Facts. Same facts as Example 3, except that E elected COBRA continuation coverage.

(ii) Conclusion. In this Example 5, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll other than as a COBRA qualified beneficiary (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 6. (i) Facts. Employer X maintains a group health plan with a calendar year plan year. Prior to 2011, the plan allows children of employees to be covered under

the plan until the child attains age 22. During the 2009 plan year, an individual with a 22-year old child joins the plan; the child is denied coverage because the child is 22.

(ii) Conclusion. In this Example 6, notwithstanding that the child was not previously covered under the plan, the plan must provide the child, not later than January 1, 2011, an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than January 1, 2011.

§ 2590.715-2801 Preservation of right to maintain existing coverage.

(a) Definition of grandfathered health plan coverage—(1) In general—(i)

Coverage provided by a group health plan, or a group or individual health insurance issuer, in which an individual was enrolled on March 23, 2010 is grandfathered health plan coverage (for as long as it maintains that status under paragraph (g) of this section), regardless of whether the individual renews the coverage after March 23, 2010. For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan.

(ii) If, on March 23, 2010, no individuals in a group health plan were enrolled in a particular policy, certificate, or contract of insurance, that policy, certificate, or contract of insurance is not a grandfathered health plan with respect to the individuals in the group health plan.

(2) Documentation of plan or policy terms on March 23, 2010. To maintain status as a grandfathered health plan, a group health plan, or group or individual health insurance coverage, must –

(i) Maintain records documenting the plan or policy terms in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(ii) Make such records available for examination.

(3) Family members enrolling after March 23, 2010. Grandfathered health plan coverage includes coverage of family members of an individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(b) Allowance for new employees to join current plan. A group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010.

(c) General grandfathering rule—(1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709, 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. In addition, the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it applies to annual limits, do not apply to grandfathered health plans that are individual health insurance coverage.

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) Provisions applicable to all grandfathered health plans. The provisions of PHS Act section 2711 insofar as it applies to lifetime limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(e) Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health coverage—(1) The provisions of PHS Act section 2704 as it applies to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent.

(f) Effect on collectively-bargained plans. In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which

the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage which amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of paragraph (g) of this section (comparing the terms of the coverage after the date the last collective bargaining agreement terminates with the terms of the coverage that were in effect on March 23, 2010).

(g) Maintenance of grandfather status—(1) Changes causing loss of grandfather status—(i) Any of the following changes in the terms of a grandfathered health plan will cause the plan or coverage to cease to be a grandfathered health plan:

(A) Any increase in a fixed-amount cost-sharing requirement (e.g., deductible, copayment, or out-of-pocket limit), determined as of the effective date of the increase, if the total increase in such requirement measured from March 23, 2010 exceeds a percentage equal to the sum of:

(1) 15 percent; and

(2) The increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI-U) (unadjusted) published by the Department of Labor using the 1982 – 1984 base of 100, expressed as a percentage. For this purpose, the increase in the overall medical care component is computed by dividing the index amount for any month in the twelve months before the new change is to take effect by 387.142 (the overall medical care component of the CPI-U (unadjusted) published by the Department of Labor for March 2010, using the 1982 – 1984 base of 100), subtracting one from that quotient, and then, to express as a percentage, multiplying by 100.

(B) Any increase in a percentage cost-sharing requirement (such as increasing an individual's 20 percent coinsurance requirement to 25 percent).

(C) The elimination of all or substantially all benefits to diagnose or treat a particular condition.

(ii) In the case of a change not described in paragraph (g)(1)(i) or (g)(2) of this section, such as an elimination of less than all or substantially all benefits to diagnose or treat a particular condition, the rules of paragraph (g)(3) of this section apply.

(2) Safe harbor: changes that do not affect grandfather status. The following changes in the terms of a grandfathered health plan do not change the status of the plan or coverage as a grandfathered health plan:

(i) Any changes in the premium that, in the individual market, a health insurance issuer charges an individual for coverage.

(ii) Any changes in the premium that, in the group market, a health insurance issuer charges an employer for coverage (or to the extent that a multiemployer plan is

self-insured, changes in the total amount that an employer is required to pay for coverage).

(iii) Any changes in the amount that an employer or employee organization contributes toward coverage (whether insured or self-insured).

(iv) Any changes in the amount that a participant is required to contribute towards coverage under a group health plan (whether insured or self-insured).

(v) Any changes to comply with Federal or State legal requirements that apply to the grandfathered health plan.

(vi) Any changes to voluntarily comply with provisions of the Patient Protection and Affordable Care Act that do not apply to the grandfathered health plan.

(vii) For the first plan year beginning on or after September 23, 2010 (in the individual market, the first policy year), replacement of a lifetime limit with an annual limit as permitted by § 2590.715-2711 of this Part.

(viii) Any decrease in cost-sharing for the individual (including the establishment of an out-of-pocket limit) or an increase in covered benefits (such as a new covered item or service).

(ix) Any increase in a fixed-amount cost-sharing requirement (e.g., deductible, copayment, or out-of-pocket limit), determined as of the effective date of the increase, if the total increase in such requirement measured from March 23, 2010 does not exceed a percentage equal to the sum of:

(A) 15 percent; and

(B) The increase since March 2010 in the overall medical care component of the CPI-U (unadjusted) published by the Department of Labor, using the 1982 – 1984 base of

100 expressed as a percentage. For this purpose, the increase is computed in the manner described in paragraph (g)(1)(i)(A) of this section.

(3) Other changes. Changes other than those described in paragraph (g)(1)(i) or (g)(2) of this section do not cause a plan (in the individual market, policy) to lose grandfather status, unless one or more of such changes (considered in the aggregate and determined cumulatively since March 23, 2010) result in the coverage under the plan (or policy) being substantially different than the coverage that was provided on March 23, 2010.

(h) The rules of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan not maintained pursuant to a collective bargaining agreement provides coverage through a group health insurance policy from Issuer X on March 23, 2010. For the plan year beginning January 1, 2012, the plan enters into a new policy with Issuer Z.

(ii) Conclusion. In this Example 1, for the plan year beginning January 1, 2012, the group health insurance coverage issued by Z is not a grandfathered health plan under the rules of paragraph (a)(1)(ii) of this section because the policy issued by Z did not provide coverage on March 23, 2010.

Example 2. (i) Facts. A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option F is a self-insured option. Options G and H are insured options. Beginning July 1, 2013, the plan replaces the issuer for Option H with a new issuer.

(ii) Conclusion. In this Example 2, the coverage under Option H is not grandfathered health insurance coverage as of July 1, 2013, consistent with the rule in paragraph (a)(1)(ii) of this section. Whether the coverage under Options F and G is grandfathered health coverage is determined under the rules of paragraph (g) of this section.

Example 3. (i) Facts. A group health plan maintained pursuant to a collective bargaining agreement provides coverage through a group health insurance policy from Issuer W on March 23, 2010. The group health plan enters into a new group health insurance policy with Issuer Y for the plan year starting on January 1, 2011. The collective bargaining agreement has not been amended and will not expire before December 31, 2011.

(ii) Conclusion. In this Example 3, the group health plan, and the group health insurance policy provided by Y, remains a grandfathered health plan with respect to existing employees and new employees and their families because the coverage is maintained pursuant to a collective bargaining agreement ratified prior to March 23, 2010 that has not terminated.

Example 4. (i) Facts. Same facts as Example 3, except the coverage with W is renewed under a new collective bargaining agreement effective January 1, 2012, with the only changes being changes described in paragraph (g)(2) of this section.

(ii) Conclusion. In this Example 4, the group health plan remains a grandfathered health plan pursuant to the rules of this section. Moreover, the group health insurance policy provided by W remains a grandfathered health plan under the rules of paragraph (g) of this section.

Example 5. (i) Facts. On March 23, 2010, a grandfathered health plan has a copayment requirement of \$30 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$35. Within the 12-month period before the \$35 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 415.

(ii) Conclusion. In this Example 5, the increase in the copayment from \$30 to \$35, expressed as a percentage is 16.67% ($35 \div 30 = 1.1667$; $1.1667 - 1 = 0.1667$; $0.1667 = 16.67\%$). The percentage increase in the overall medical care component of the CPI-U (unadjusted) from March 2010 is 7.20% ($415 \div 387.142 = 1.0720$; $1.0720 - 1 = 0.0720$; $0.0720 = 7.20\%$). The maximum percentage increase that would be permitted under paragraph (g)(1)(i)(A) is 22.20% ($15\% + 7.20\% = 22.20\%$). Because 16.67% does not exceed 22.20%, the change in the copayment requirement at that time does not cause the grandfathered health plan to lose grandfathered status.

From: [Mayhew, James A. \(CMS/CPC\)](#)
To: [Lucia, Kevin \(HHS/OCIIO\)](#)
Subject: FW: Clean and Redline versions from today
Date: Thursday, May 06, 2010 6:20:00 PM
Attachments: [Joint Preamble 4.23.10 7pm clean.doc](#)
[Reg Text 4.23.10 7pm clean.doc](#)

Here's the preamble and reg text of 2711, 2712, 2713, 2704, 2716, and 1251 when bundled together.

[Billing Codes: 4830-01-P; 4510-29-P; 4120-01-P]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

TD

RIN 1545-BJ46

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB41

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

OCIIO-

45 CFR Part 146

RIN 0938-

Interim Final Rules for Group Health Plans and Health Insurance Issuers under the Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the requirements for group health plans and health insurance issuers in the group and individual markets under provisions of the Patient Protection and Affordable Care Act (the Affordable Care Act) regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, coverage of certain preventive health services without cost-sharing, coverage of dependent children to age 26, and discrimination in favor of highly compensated individuals. These interim final regulations also provide guidance on grandfathered health plans under the Affordable Care Act.

DATES: Effective date. These interim final regulations are effective on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Comment date. Comments are due on or before **[INSERT DATE 90 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Applicability date. These interim final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after September 23, 2010. These interim final regulations generally apply to individual health insurance issuers for policy years beginning on or after September 23, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines.

No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB41, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Email: E-OHPSCA.EBSA@dol.gov.

- Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: RIN 1210-AB41.

Comments received by the Department of Labor will be posted without change to www.regulations.gov and www.dol.gov/ebsa, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIIO-[REDACTED]. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.
2. By regular mail. You may mail written comments to the following address ONLY:
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services,

Attention: OCIIO- [REDACTED],

P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services,

Attention: OCIIO- [REDACTED],

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to

leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the

headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-114494-10, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: CC:PA:LPD:PR (REG-114494-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-114494-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; [INSERT], Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at [INSERT].

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's website (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for

consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp).

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions in Part A of Title XXVII of the Public Health Service Act (PHS Act) relating to group health plans¹ and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of Part A of Title XXVII of the PHS Act applicable under ERISA and the Code to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if those provisions of the PHS Act were included in ERISA and the Code. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes. Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, specifies that certain plans or coverage existing as of the date of enactment (i.e., grandfathered health plans) are only subject to certain provisions.

¹ The term “group health plan”, which includes both insured and self-insured group health plans and is used in Title XXVII of the PHS Act, Part 7 of ERISA, and Chapter 100 of the Code, is distinct from the term “health plan” used in Title I of the Affordable Care Act, which does not include self-insured group health plans.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of Title XXVII of the PHS Act (changes of which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of the Affordable Care Act are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers stricter requirements than what is required by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) expect to issue regulations implementing the revised PHS Act sections 2701 through 2719A in several phases. The first publication in this series was a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the Federal Register on April 14, 2010 (75 FR 19297). This document contains interim final regulations implementing PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding rescissions), 2713 (requiring coverage of certain preventive health services without cost-sharing), 2714 (requiring dependent coverage of children to age 26), and 2716 (prohibiting discrimination in favor of highly compensated individuals). These interim final regulations also provide guidance on the rules of section 1251 of the Affordable Care Act regarding grandfathering of group health plans and health insurance coverage and on the requirement to provide enrollment opportunities to

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in Chapter 100 of the Code.

individuals who reached a lifetime limit or who lost or were not eligible for dependent coverage before age 26. These provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions in PHS Act sections 2701 through 2719A will be addressed in future regulations.

Because subtitles A and C of title I of the Affordable Care Act contain requirements that are applicable to both the group and individual health insurance markets, it would be duplicative to insert the requirements into both the existing 45 CFR Part 146 (Requirements for the Group Health Insurance Market) and 45 CFR Part 148 (Requirements for the Individual Health Insurance Market). Accordingly, these interim final regulations create a new Part 147 in Subchapter B of 45 CFR to implement these provisions of the Affordable Care Act. These provisions, to the extent that they apply to group health plans and group health insurance coverage, are also implemented under new provisions added to 29 CFR Part 2590 and 26 CFR Part 54.

II. Overview of the Regulations

A. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815-2704, 29 CFR 2590.715-2704, 45 CFR 147.2704)

Section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA³ rules relating to preexisting conditions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under

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³ HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

certain circumstances. The Affordable Care Act provision prohibits any preexisting condition exclusions imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

HIPAA generally defines a preexisting condition exclusion⁴ as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

For group health plans and group health insurance issuers, a denial of coverage of an individual based on a preexisting condition exclusion also violates the HIPAA rules prohibiting discrimination based on a health factor. Beginning on January 1, 2014, a denial of coverage of an individual based on a preexisting condition would also violate more than one provision in the individual market: the prohibition against preexisting condition exclusions, the guaranteed availability requirement, and the prohibition against discrimination based on health status. Of course, if an individual was denied coverage beginning in 2014 on a ground other than the existence of a preexisting condition or a health factor, the denial would only violate the right to guaranteed availability.

⁴ Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1); after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1). See also ERISA section 701(b)(1) and Code section 9801(b)(1).

The protections in the new PHS Act section 2704 generally apply to plan years (in the individual market, policy years) beginning on or after January 1, 2014. The Affordable Care Act provides, however, that these protections apply with respect to enrollees under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. An enrollee under age 19 thus could not be denied benefits based on a preexisting condition. In order for an individual to receive the same protection that applies in the case of such an enrollee, the individual similarly could not be denied benefits (in whole or part) based on a preexisting condition. Thus, for plan years (in the individual market, for policy years) beginning on or after September 23, 2010, PHS Act section 2704 protects individuals under age 19 with a preexisting condition from being denied coverage under a plan (in whole or part) based on their preexisting conditions.

These interim final regulations do not change the HIPAA rule that a plan's or issuer's exclusion of benefits for a condition from the plan or policy regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. This point is still relevant for these interim final regulations and is illustrated with examples in the HIPAA regulations on preexisting condition exclusions.⁵ (Other requirements of Federal or State law, however, may prohibit certain benefit exclusions.)

Application to grandfathered health plans. A grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704. See 26 CFR 54.9815-2801, 29 CFR 2590.715-2801, and 45 CFR 147.2801 regarding grandfathered health plans.

⁵ See Examples 6, 7, and 8 in 26 CFR 54.9801-3(a)(1)(ii), 29 CFR 701-3(a)(1)(ii), 45 CFR 146.111(a)(1)(ii).

B. PHS Act Section 2711, No Lifetime or Annual Limits (26 CFR 54.9815-2711, 29 CFR 2590.715-2711, 45 CFR 147.2711)

Section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits. However, these interim final regulations provide that the annual limit rules do not apply to health flexible spending arrangements.⁶

The statute also allows “restricted annual limits” with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. In addition, the statute provides that, with respect to benefits that are not essential health benefits, a plan or issuer may impose annual or lifetime per individual limits on specific covered benefits. Rather than provide a definition of “essential health benefits,” these interim final regulations cross-reference section 1302(b) of the Affordable Care Act and applicable regulations.⁷

These interim final regulations clarify that the prohibition under PHS Act section 2711 does not prevent a plan or issuer from excluding all benefits for a condition, but if any benefits are provided for a condition, then the requirements of the rule apply. Therefore, an exclusion of all benefits for a condition is not considered to be an annual or lifetime dollar limit.

The statute and these interim final regulations provide that for plan years (in the individual market, policy years) beginning before January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may only establish a restricted annual limit on the dollar value of essential health benefits. The statute provides that

⁶ Section 9005 of the Affordable Care Act specifically limits the annual amount of salary reduction contributions for health flexible spending arrangements.

⁷ Regulations under section 1302(b) of the Affordable Care Act have not yet been issued.

in defining the term “restricted annual limit,” the Departments “ensure that access to needed services is made available with a minimal impact on premiums.”

In establishing the restricted annual limit, the Departments considered several factors: (1) the current use of annual limits in the group and individual market; (2) the average premium impact of imposing different annual limits on the individual, small group, and large group markets; (3) the number of individuals who will continue to have annual medical expenses that exceed an annual limit; and (4) the possibility that a plan or issuer would switch to an annual limit when lifetime limits are prohibited.

Approximately four percent of large employer plans, eight percent of small employer PPO plans, and 19 percent of individual market plans currently have annual limits. Although available data show that very few health insurance plans impose annual limits, at least half of small group plans and over 75 percent of policies in the individual market impose lifetime limits. The 2009 Kaiser Family Foundation/HRET Survey of Employers found that less than one percent of covered workers had lifetime limits less than \$1 million, 16 percent had limits between \$1 million and \$1.99 million, 43 percent had lifetime limits of \$2 million or more, and 41 percent had no lifetime maximum.⁸ Of those enrollees in indemnity plans with lifetime limits, 63 percent of single enrollees and 44 percent of family enrollees had lifetime maximums less than \$2 million while less than one percent of enrollees in network-based arrangements, such as HMOs, PPOs, or high deductible health plans with savings options had lifetime maximums less than \$2 million. While it is possible that those plans with lifetime limits will switch to annual limits prior to the elimination of annual limits in 2014, group health plans and

⁸ See the Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), at <http://ehbs.kff.org/pdf/2009/7936.pdf>.

health insurance issuers could use a number of changes to benefit design to mitigate any potential premium increases.

Comment [b1]: Can we get rid of this whole paragraph? Cross reference the discussion in the economic analysis that goes over these same statistics?

If not, use cite for the 1st sentence from economic analysis cite to Mercer survey (FN 31 in old draft)

In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, these interim final regulations adopt a three-year phased approach for restricted annual limits. This phased-in approach provides ample opportunity for plans with relatively low annual limits (e.g., \$100,000, \$250,000, or \$500,000) to more gradually make adjustments that might smooth any increase in costs that might result from the increased minimum annual limits under these interim final regulations. The proposed annual limit levels ensure that the vast majority of individuals who may experience high medical costs during the year will continue to have access to coverage.

These interim final regulations provide the following minimum amounts for annual limits on the dollar value of benefits that are essential health benefits for plan years (in the individual market, policy years) beginning before January 1, 2014:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, \$750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, \$1.25 million; and
- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2 million.

As these are minimums for plan years (in the individual market, policy years) beginning before 2014, plans or issuers may always use higher annual limits or impose no limits. Plans and policies with plan or policy years that begin between September 23 and December 31 have more than one plan or policy year under which the \$2 million minimum annual limit is available;

however, a plan or policy generally may not impose an annual limit for a plan year beginning after December 31, 2013.

The minimum annual limits for plan or policy years beginning before 2014 apply on an individual-by-individual basis. Thus, any overall annual dollar limit on benefits applied to families may not operate to deny a covered individual the minimum annual benefits for the plan year (in the individual market, policy year). These interim final regulations clarify that, in applying annual limits for plan years (in the individual market, policy years) beginning before January 1, 2014, the plan (or policy) may only take into account essential health benefits.

These interim final regulations provide an enrollment (in the individual market, reinstatement) opportunity for individuals who reached their lifetime limits in a group health plan or health insurance coverage and remain otherwise eligible for the coverage. In the individual market, this reinstatement opportunity does not apply to individuals who reached their lifetime limits in individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in a family policy in the individual market while other family members remain in the coverage. This opportunity must be made available no later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. See discussion of transitional rules in Section II.G. of this preamble.

Application to grandfathered health plans. The statute and these interim final regulations relating to the prohibition on lifetime limits apply to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the

prohibition on annual limits, including the special rules regarding restricted annual limits for plan years beginning before January 1, 2014, apply to group health plans and group health insurance coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage.

C. PHS Act Section 2712, Rescissions (26 CFR 54.9815-2712, 29 CFR 2590.715-2712, 45 CFR 147.2712)

PHS Act section 2712 provides rules regarding rescissions⁹ of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard applies to all rescissions, whether in the group or individual insurance market, or self-insured coverage. These rules also apply regardless of any contestability period of the plan or issuer.

These interim final regulations include several clarifications regarding the standards for rescission. First, these interim final regulations clarify that the rules of PHS Act section 2712 apply whether the rescission applies to a single individual or an entire group of individuals. Thus, for example, if an issuer attempted to rescind coverage of an entire employer group based on the actions of an individual within the group, the standards of these interim final regulations would apply. Second, these interim final regulations clarify that the rules of PHS Act section 2712 apply to representations made by the individual or a person seeking coverage on behalf of the individual. Thus, if a plan sponsor seeks coverage from an issuer for an entire employment-based group and makes representations, for example, regarding the prior claims experience of the

⁹ For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission.

group, the standards of these interim final regulations would also apply. Finally, PHS Act section 2712 refers to acts or practices that constitute fraud. These interim final regulations clarify that, to the extent that an omission constitutes fraud, that omission would permit the plan or issuer to rescind coverage under this section. An example in these interim final regulations illustrates the application of the rule to misstatements of fact that are inadvertent.

PHS Act section 2712 adds a new advance notice requirement when coverage is rescinded where still permissible. Specifically, the second sentence in section 2712 provides that coverage may not be cancelled unless prior notice is provided, and then only as permitted under PHS Act sections 2702(c) and 2742(b). Under these interim final regulations, even if prior notice is provided, rescission is only permitted in cases of fraud or an intentional misrepresentation of a material fact as permitted under the cited provisions.¹⁰ While this reference appears redundant, it is consistent with the first sentence.

These interim final regulations provide that a group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 days advance notice to an individual before coverage may be rescinded.¹¹ The notice must be provided regardless of whether the rescission is of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group.

¹⁰ The reference to section 2702(c) appears to be incorrect. After the amendments made by the Affordable Care Act, PHS Act section 2702(c) addresses network requirements for guaranteed availability of coverage. It seems more likely that the intended cross-reference is to new PHS Act section 2703(b), relating to nonrenewal of coverage in the group market, which corresponds to the other cross-reference, in PHS Act section 2742(b), to nonrenewal of coverage in the individual market. Both these provisions contain the fraud and intentional misrepresentation of material fact standard included in the first sentence of section 2712. In order to avoid confusion, these interim final regulations apply the fraud and misrepresentation standard found in sections 2703(b) and 2742(b).

¹¹ Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

These interim final regulations also clarify that other requirements of Federal or State law may apply in connection with a rescission of coverage, including the requirement under PHS Act section 2719(a)(1)(C), which requires a plan or an issuer to allow an enrollee to continue coverage pending the outcome of an appeal of a coverage or claim determination. Regulatory guidance regarding the provisions of PHS Act section 2719 is expected to be issued in the near future.

Application to grandfathered health plans. The rules regarding rescissions and advance notice apply to all grandfathered health plans.

D. PHS Act 2713, Coverage of Preventive Health Services (26 CFR 54.9815-2713, 29 CFR 2590.715-2713, 45 CFR 147.2713)

Section 2713 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations require that a group health plan and a health insurance issuer offering group or individual health insurance coverage provide coverage of certain preventive health care services, and prohibit the imposition of cost-sharing in connection with these services.

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The statute and these interim final regulations require coverage of the following:

- Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force.¹²
- Immunizations for routine use in children, adolescents and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved. A recommendation of the the Advisory Committee on Immunization Practices of the

¹² Under PHS Act section 2713(a)(5), United States Preventive Services Task Force recommendations regarding breast cancer screening, mammography, and prevention issued in or around November of 2009 are not to be considered current recommendations on this subject for purposes of PHS Act section 2713(a)(1). Thus, the recommendations regarding breast cancer screening, mammography, and prevention issued by the task force prior to those issued in or around November of 2009 (that is, those issued in 2002) will be considered current until new recommendations in this area are issued by the task force.

Centers for Disease Control and Prevention is considered to be “in effect” after it has been adopted by the Director of the Centers for Disease Control and Prevention.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported Health Resources and Services Administration. Currently, these are the guidelines included as part of the Bright Futures Initiative sponsored by the Health Resources and Services Administration and the American Academy of Pediatrics.
- Health Resources and Services Administration guidelines concerning preventive care and screenings for women (not otherwise addressed by the recommendations of the United States Preventive Services Task Force). No such guidelines currently exist, although the Department of HHS is considering options for developing these guidelines in the near term.

The complete list of recommendations and guidelines that are required to be covered under these provisions can be found at [<http://www.hhs.gov/ociio/regulations/prevention/>]. The statute and these interim final regulations clarify that a plan or issuer may cover preventive services in addition to those required to be covered by PHS Act section 2713.

The statute requires the Departments to establish an interval of not less than one year between when recommendations or guidelines under PHS Act section 2713(a)¹³ are issued, and

¹³ Section 2713(b)(1) refers to an interval between “the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.” While the first part of this statement does not mention guidelines under subsection (a)(4), it would make no sense to treat the services covered under (a)(4) any differently than those in (a)(1), (a)(2), and (a)(3). First, the same sentence refers to “the requirement described in subsection (a),” which would include a requirement under (a)(4). Secondly, the guidelines under (a)(4) are from the same source as those under (a)(3), except with respect to women rather than infants, children and adolescents; and other preventive services involving women are addressed in (a)(1), so there is no plausible policy rationale for treating them differently. Most importantly, if the “interval” under section 2713(b) did not govern when services had to be covered under section 2713(a)(4), it is not clear when such services would have to be covered. It would make no sense to take the position that they had to be covered

the plan year (in the individual market, policy year) for which coverage of the services addressed in such recommendations or guidelines must be in effect. These interim final regulations provide that such coverage must be provided for plan years (in the individual market, policy years) beginning on or after the later of September 23, 2010, or one year after the date the recommendation or guideline is issued. Thus, recommendations and guidelines issued prior to September 23, 2009 must be provided for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

Finally, these interim final regulations make clear that a plan or issuer is not required to provide coverage for any recommendation or guideline after the recommendation or guideline is no longer described in paragraph (a) of this section,¹⁴ but other requirements of Federal or State law may apply in connection with ceasing to provide coverage for any such recommendation or guideline, including the requirement under PHS Act section 2715(d)(4), which requires a plan or an issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

Application to grandfathered health plans. The requirements to cover these preventive health services without any cost-sharing do not apply to grandfathered health plans.

E. PHS Act Section 2714, Continued Eligibility of Children until Age 26 (26 CFR 54.9815-2714, 29 CFR 2590.715-2714, 45 CFR 147.2714)

Section 2714 of the PHS Act, as added by the Affordable Care Act (and amended by the Reconciliation Act), and these interim final regulations provide that a plan or issuer that makes available dependent coverage for children must allow dependent coverage for children until

upon enactment, on March 23, 2010, or to say that because they are not addressed in section 2713(b) they would never have to be covered. Yet, if the interval in section 2713(b) did not apply, it is not clear what other date would govern. These interim final regulations accordingly apply the intervals established therein to services under 2713(a)(4).

¹⁴ For example, if a recommendation of the United States Preventive Services Task Force is downgraded from a rating of A or B to a rating of C or D, or if a recommendation or guideline is superseded by a more current recommendation or guideline.

attainment of 26 years of age. The statute also authorizes the Departments to issue regulations to “define the dependents to which coverage shall be made available” under this rule. These interim final regulations clarify that with respect to children who have not attained age 26, a plan or issuer may not define dependent for purpose of eligibility for coverage other than in terms of the relationship between the child and the participant (in the individual market, the primary subscriber). Examples of factors that cannot limit dependent status include financial dependency, residency with the participant or primary subscriber, student status, employment status, eligibility for other coverage, or any combination of these. These interim final regulations also provide that the terms of the plan or policy for dependent coverage cannot vary based on the age of a child, except for children age 26 or older. Examples illustrate that surcharges for coverage of additional children are not allowed except where the charges apply regardless of the age of the child under age 26 and that the plan cannot vary benefits based on the age of the child under age 26.

Before the enactment of the Affordable Care Act, many group health plans that provided dependent coverage limited the coverage to health coverage excludible from employees’ gross income for income tax purposes. Thus, dependent coverage was limited to employees’ spouses and employees’ children that qualify as dependents for income tax purposes. Consequently, these plans often conditioned dependent coverage, in addition to the age of the child, on student status, residency and financial support or other requirements indicating dependent status. However, with the expansion of dependent coverage required by the Affordable Care Act to children until age 26, whether a child is a dependent is no longer an appropriate factor and may in fact be a proxy for age used to circumvent the new rule. Therefore, these interim final regulations do not allow plans or coverage to use these requirements to deny dependent coverage

to children. Not only are these factors no longer appropriate in determining eligibility for adult children, these factors also may not be used to determine eligibility for dependent coverage for minor children. The statute and these interim final regulations provide that nothing in PHS Act section 2714 requires a plan or issuer to make available coverage for a child of a child receiving dependent coverage.

Application to grandfathered health plans. The statute and these interim final regulations provide that the requirement to make available dependent coverage for children who have not attained age 26 generally applies to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. For plan years beginning before January 1, 2014, these interim final regulations provide that a grandfathered health plan that is a group health plan may exclude an adult child who has not attained age 26 from coverage only if the child is eligible to enroll in an employer-sponsored health plan (as defined in section 5000A(f)(2) of the Code) other than a group health plan of a parent. Thus, in the case of an adult child who is eligible for coverage under the employer-sponsored plans of both parents, neither parent's plan may exclude the adult child from coverage based on the fact that the adult child is eligible to enroll in the other parent's employer-sponsored plan. These interim final regulations also provide an enrollment opportunity for children excluded from coverage because of age before the effective date of the rule.

F. PHS Act Section 2716, Prohibiting Discrimination in Favor of Highly Compensated Individuals (26 CFR 54.9815-2716, 29 CFR 2590.715-2716, 45 CFR 147.2716)

PHS Act section 2716 and these interim final regulations incorporate the nondiscrimination rules of section 105(h) of the Code and apply them to group health plans that

are not self-insured plans. Section 105(h) generally prohibits self-insured medical reimbursement plans from discriminating in favor of highly compensated individuals in eligibility classifications or in benefits. Section 105(b) of the Code generally excludes from an employee's income (otherwise subject to federal income taxation) amounts received as reimbursement of medical care expenses for the employee or the employee's spouse, dependents, or children who have not attained age 27 by the end of the taxable year. If a self-insured medical reimbursement plan does not comply with the requirements of section 105(h), the general exclusion from income (and hence, from federal income taxation) under section 105(b) does not apply with respect to highly compensated individuals. Highly compensated individuals are defined in section 105(h).

PHS Act section 2716 and these interim final regulations incorporate the substantive nondiscrimination requirements of Code section 105(h) but not the tax sanctions. An insured group health plan failing to comply with the nondiscrimination requirements of Code section 105(h) is subject to the sanctions and remedies that generally apply for a plan failing to comply with the requirements of chapter 100 of the Code (generally, an excise tax of \$100 per day per individual for each day the plan does not comply with the requirement), part 7 of ERISA (a civil action to enjoin a noncompliant act or practice or for appropriate equitable relief), or Title XXVII of the PHS Act (civil money penalties of \$100 per day per individual for each day the plan does not comply with the requirement). Thus, if a self-insured plan fails to comply with Code section 105(h), highly compensated individuals lose a tax benefit; if an insured group health plan fails to comply with Code section 105(h), the plan is subject to a civil action to compel it to provide nondiscriminatory benefits and the plan or plan sponsor is subject to an excise tax or civil money penalty of \$100 per day per individual. Rather than restate the rules

under section 105(h) of the Code, these interim final regulations incorporate by reference those rules and applicable regulations.

Application to grandfathered health plans. The rules prohibiting discrimination in favor of highly compensated individuals do not apply to grandfathered health plans (but the rules of Code section 105(h) continue to apply to self-insured plans).

G. Transitional Rules for Individuals Who Reached a Lifetime Limit or a Dependent Eligibility Threshold (26 CFR 54.9815-2800, 29 CFR 2590.715-2800, 45 CFR 147.2800)

Certain new provisions of the PHS Act can affect individuals who previously were covered and lost coverage under a group health plan (in the individual market, policy) or were never eligible for coverage (including individuals denied coverage in the individual market). For example, prior to the applicability date of PHS Act section 2711, an individual may have reached a lifetime limit under a group health plan or health insurance coverage and therefore lost coverage under the plan or coverage. When the provisions of PHS Act section 2711 become applicable to the plan (or coverage), the plan (or coverage) can no longer exclude coverage for the individual by operation of the lifetime limit. Similarly, prior to the applicability date of PHS Act section 2714, an individual who was covered under a group health plan or health insurance coverage as a dependent may have lost eligibility under the plan (or coverage) due to age prior to age 26. Moreover, if, when a parent first became eligible for coverage, a child was under age 26 but older than the age at which the plan (or coverage) stopped covering children, the child would not have become eligible for the plan (or coverage). When the provisions of PHS Act section 2714 become applicable, a plan or issuer can no longer exclude coverage for the individual prior to age 26. Finally, a family member covered through a family policy in the individual market

may be entitled to an opportunity to enroll if the family member is a dependent who previously lost coverage due to age while other family members remained in the coverage.¹⁵

Accordingly, these interim final regulations provide transitional relief for an individual – (1) whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits for any individual; or (2) whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26.

These interim final regulations require a plan or issuer to give such an individual an opportunity to enroll that continues for at least 30 days (including notice of the opportunity to enroll), regardless of whether the plan or coverage offers an open enrollment period and regardless of when any open enrollment period might otherwise occur. This enrollment opportunity must be presented not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010 (which is the applicability date of PHS Act sections 2711 and 2714). Coverage must begin not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, even if it means that the coverage must be retroactive.

Any individual enrolling in group health plan coverage pursuant to this enrollment right must be treated as a special enrollee, as provided under the HIPAA portability rules.¹⁶

Accordingly, the individual must be offered all the benefit packages available to similarly

¹⁵ In the group market, section 9802(a) of the Code, section 702(a) of ERISA, and section 2705 of the PHS Act provide that a plan or issuer cannot impose any rule for eligibility for benefits (including any rule excluding coverage) based on a health factor, including a preexisting condition. These rules were added by HIPAA and generally became applicable for group health plans for plan years beginning on or after July 1, 1997. Similar guidance regarding re-enrollment rights for individuals previously denied coverage due to a health factor was issued by the Departments of the Treasury, Labor, and HHS on December 29, 1997, at 62 FR 67689 and on January 8, 2001 at 66 FR 1378, 1403, 1410, 1418.

¹⁶ See 26 CFR 54.9801-6(d), 29 CFR 701-6(d), 45 CFR 146.117(d).

situated individuals who did not lose coverage due to reaching a lifetime limit or cessation of dependent status. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage due to reaching a lifetime limit or cessation of dependent status.

Examples in these interim final regulations illustrate the application of these transitional rules. One example illustrates that, if a dependent child qualifies for an enrollment opportunity under this section and the parent is not enrolled but otherwise eligible for enrollment, the plan must provide an opportunity to enroll the parent, in addition to the dependent child. Similarly, another example illustrates that, if a plan has more than one benefit package option, a dependent child qualifies for enrollment under this section, and the parent is enrolled in one benefit package option, the plan must provide an opportunity to enroll the dependent in any benefit package option for which the dependent is otherwise eligible (thus allowing the parent to switch benefit package options). Another example illustrates that dependent children covered under a COBRA continuation provision must be given the opportunity to enroll as a dependent of an active employee. In this situation, if the child loses eligibility for coverage due to a qualifying event (including aging out of coverage at age 26), the child has another opportunity to elect COBRA continuation coverage. If the qualifying event is aging out, the COBRA continuation coverage could last 36 months from the loss of eligibility that relates to turning age 26. The final example in this section illustrates that an employee who joined a plan prior to the applicability date of PHS Act section 2714, and has a dependent child who never enrolled because the child was too old under the terms of the plan but has not yet turned 26, has another opportunity to enroll the child under this section even though the child was not previously covered under the plan. If the

parent is no longer eligible for coverage under the plan (for example, if the parent has ceased employment with the plan sponsor), the plan would not be required to enroll the child.

Application to grandfathered health plans. The requirement to give enrollment opportunities to individuals who reached a lifetime limit applies to all grandfathered health plans. The requirement to give enrollment opportunities to individuals who are denied dependent coverage (or who are not eligible for dependent coverage) of a child prior to age 26 applies to all grandfathered health plans that are group health plans or group health insurance coverage, but does not apply to grandfathered health plans that are individual health insurance coverage.

H. Section 1251 of the Affordable Care Act, Preservation of Right to Maintain Existing Coverage (26 CFR 54.9815-2801, 29 CFR 2590.715-2801, 45 CFR 147.2801)

Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and Reconciliation Act section 2301, provides that certain plans existing as of March 23, 2010 (the date of enactment of the Affordable Care Act), are only subject to certain provisions of the Affordable Care Act. The statute and these interim final regulations refer to these plans as grandfathered health plans. The statute and these interim final regulations provide that a group health plan or group or individual health insurance coverage is a grandfathered health plan with respect to individuals enrolled on March 23, 2010 regardless of whether the individual later renews the coverage, subject to rules that disqualify a plan or coverage from the exception for grandfathered health plans if the plan or coverage makes certain changes.

To maintain status as a grandfathered health plan, under these interim final regulations, a plan or issuer must maintain records documenting the plan or policy terms in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan. In addition, the plan or issuer must make such records available for examination. Accordingly, a participant, beneficiary, individual policy

subscriber, State or Federal agency official would be able to inspect such documents to verify grandfathered status.

The statute and these interim final regulations allow family members of individuals who are enrolled in a grandfathered plan to enroll in the plan after March 23, 2010; in such cases, the plan or coverage is also a grandfathered health plan with respect to the family members.

In addition, the statute and these interim final regulations provide that a group health plan that provided coverage on March 23, 2010 generally is also a grandfathered health plan with respect to new employees (whether newly hired or newly enrolled) and their families that enroll in the grandfathered health plan after March 23, 2010; these interim final regulations clarify that in such cases any health insurance coverage provided under the group health plan in which an individual covered under the group health plan was enrolled on March 23, 2010 is also a grandfathered health plan.

The Departments are considering whether the regulations should include measures to prevent an employer from taking advantage of a plan's grandfathered status to enroll large numbers of employees of other employers. In particular, the Departments are considering adopting a final rule under which the enrollment of employees of employers who did not maintain the plan on March 23, 2010 should result in a loss of the plan's grandfathered status, unless the new employers are members of a control group or otherwise share substantial business interests unrelated to the plan. In addition, the Departments are considering adopting a final rule under which inordinate growth of a plan within a single plan year, other than by enrolling new employees of the original sponsoring employers and their families, should affect the plan's grandfathered status. The Departments solicit comments on whether, for example, a plan that grows by the greater of 200 participants or 200 percent within a plan year (not counting new

employees of the original sponsors) should be regarded as so different that it is no longer the same plan for purposes of the grandfather rules of section 1251 of the Affordable Care Act. The Departments also solicit comments on this and other appropriate measures to discourage abuse of grandfathered status.

A special rule for collectively bargained plans provides that, in the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements ratified before March 23, 2010, the coverage is a grandfathered health plan at least until the date on which the last agreement relating to the coverage that was in effect on March 23, 2010 terminates. Thus, before the applicable collective bargaining agreement terminates, any health insurance coverage provided pursuant to the collective bargaining agreement is a grandfathered health plan. After the date on which the last of the collective bargaining agreements terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of paragraph (g) of this section. This determination is made by comparing the terms of the coverage after the date the last collective bargaining agreement terminates with the terms of the coverage that were in effect on March 23, 2010.

A grandfathered health plan generally is not subject to subtitles A and C of title I of the Affordable Care Act, except as specifically provided by the statute and these interim final regulations. The statute and these interim final regulations provide that some provisions of subtitles A and C of title I of the Affordable Care Act continue to apply to all grandfathered health plans and some provisions continue to apply only to grandfathered health plans that are group health plans. These interim final regulations clarify that, to the extent not inconsistent with the provisions that continue to apply to a grandfathered health plan, a grandfathered health

plan must continue to comply with the requirements of the PHS Act, ERISA, and the Code that were applicable prior to the changes enacted by the Affordable Care Act.

The following table summarizes the application of the Affordable Care Act's health coverage reforms that apply to grandfathered plans:

PHS Act Section	Provision	Application to Grandfathered plans	Applies for PY ¹⁷ Beginning on or after
§2701	Fair health insurance premiums	Not applicable	January 1, 2014
§2702	Guaranteed availability of coverage	Not applicable	January 1, 2014
§2703	Guaranteed renewability of coverage	Not applicable	January 1, 2014
§2704	Prohibition of preexisting condition exclusion or other discrimination based on health status	Applicable to grandfathered group health plans and group health insurance coverage. Not applicable to grandfathered individual health insurance coverage.	January 1, 2014 For individuals under age 19, September 23, 2010
§2705	Prohibiting discrimination against individual participants and beneficiaries based on health status	Not applicable	January 1, 2014
§2706	Nondiscrimination in health care	Not applicable	January 1, 2014
§2707	Comprehensive health insurance coverage (applicable to issuers in the individual and small group markets)	Not applicable	January 1, 2014
§2708	Prohibition on excessive waiting periods	Applicable	January 1, 2014
§2709	Coverage for individuals participating in approved clinical trials	Not applicable	January 1, 2014
§2711	No lifetime or annual limits	Lifetime limits: Applicable Annual limits: Applicable to grandfathered group health plans and group health insurance coverage; not applicable to grandfathered individual health insurance coverage. ¹⁸	September 23, 2010
§2712	Prohibition on Rescissions	Applicable	September 23, 2010
§2713	Coverage of preventive health	Not applicable	September 23, 2010

¹⁷ As used in this chart, PY refers to plan year (in the individual market, policy year).

¹⁸ Restricted annual limits may be imposed for plan or policy years beginning before January 1, 2014 in amounts specified in these interim final regulations.

§2714	Extension of dependent coverage	Applicable ¹⁹	September 23, 2010
§2715	Development and utilization of uniform explanation of coverage documents and standardized definitions	Applicable	September 23, 2010
§2715A	Provisions of additional information	Not applicable	September 23, 2010
§2716	Prohibition of discrimination based on salary (not applicable to self-insured plans)	Not applicable	September 23, 2010
§2717	Ensuring quality of care	Not applicable	September 23, 2010
§2718	Bringing down cost of health care coverage (for insured coverage)	Applicable to insured grandfathered plans	September 23, 2010
§2719	Appeals process	Not applicable	September 23, 2010
§2719A	Patient Protections	Not applicable	September 23, 2010

These interim final regulations include rules for determining when changes to the terms of the grandfathered health plan cause the plan or coverage to cease to be a grandfathered health plan. These rules specify certain changes that cause a plan to lose status as a grandfathered health plan, and also changes that will not cause a plan to lose status as a grandfathered health plan.

Specifically, paragraph (g)(1) of this section of these interim final regulations provides that a grandfathered health plan will lose grandfather status if there is an increase, since March 23, 2010, in a fixed-amount cost-sharing requirement that is greater than 15 percent plus the increase in the overall medical care component of the Consumer Price Index for All Urban Consumers (unadjusted) published by the Department of Labor (CPI) since March 2010. Fixed-amount cost-sharing includes, for example, a \$500 deductible, a \$30 copayment, or a \$2,500 out-of-pocket limit. The Departments acknowledge that medical inflation, as determined by the

¹⁹ For grandfathered group health plans and group health insurance issuers, for plan years beginning before January 1, 2014, PHS Act section 2714 is applicable in the case of an adult child only if the adult child is not eligible for other employer sponsored health plans coverage (as described in these interim final regulations). These interim final regulations clarify that, in the case of an adult child who is eligible for coverage under the employer-sponsored plans of both parents, neither parent's plan may exclude the adult child from coverage based on the fact that the adult child is eligible to enroll in the other parent's employer-sponsored plan.

overall medical component of CPI, does not parallel medical inflation for any particular item or service. Accordingly, to smooth out some of these differences, these interim final regulations do not automatically cause grandfathered health plans to lose their grandfathered status if a plan or issuer raises an individual copayment or other fixed-amount cost-sharing by more than the overall rate of medical inflation. Instead, these interim final regulations provide that an increase in a deductible, copayment, or other fixed-amount cost-sharing will cause a plan to lose grandfathered status if the increase exceeds 15 percent plus the rate of medical inflation (as determined using the formula set forth in the regulations). Paragraph (g)(2) of this section of these interim final regulations provides that an increase that does not exceed this amount does not cause a grandfathered health plan to lose its grandfathered status.

In addition, paragraph (g)(1) of this section of these interim final regulations provides that an increase in a percentage cost-sharing requirement (such as increasing an individual's 20 percent coinsurance requirement to 25 percent) will cause a plan to lose grandfathered status. These cost-sharing arrangements already take into account, to some degree, medical inflation. That is, to the extent the cost of a medical item or service increases, an individual may be required to pay more for it under a percentage cost-sharing requirement. Accordingly, percentage cost-sharing requirements are treated differently than fixed-amount cost-sharing under the grandfather provisions of these interim final regulations.

These interim final regulations also provide that the elimination of all or substantially all benefits to diagnose or treat a particular condition will cause a plan to lose grandfathering, regardless of whether the change is considered a substantial change overall under the plan. Therefore, for example, if a plan eliminates all benefits for cystic fibrosis, which affects relatively few individuals covered under the plan, the plan will cease to be a grandfathered health

plan, even if that change in benefit design is not considered a substantial change under paragraph (g)(3) of this section of these interim final regulations.

Paragraph (g)(2) of this section of these interim final regulations sets forth changes that do not affect grandfathered status. Specifically, the following changes do not affect grandfathered status: changes in the premiums charged by an issuer for coverage; changes in the amount that an employer or employee organization contributes toward coverage; changes to comply with applicable Federal or State legal requirements; changes to voluntarily comply with provisions of the Affordable Care Act that do not apply to grandfathered health plans; replacing a lifetime limit with an annual limit as permitted by 26 CFR 54.9815-2711, 29 CFR 2590.715-2711, or 45 CFR 147.2711 (discussed earlier in this preamble); or any decrease in cost-sharing for the individual or an increase in covered benefits.

For other changes, paragraph (g)(3) of this section of these interim final regulations provides a general standard for determining whether the plan or coverage is the same plan or coverage in which an individual was enrolled on March 23, 2010. Specifically, paragraph (g)(3) provides that a change not described in paragraph (g)(1) or (g)(2) of this section does not cause a plan (in the individual market, policy) to lose grandfathered status, unless one or more of such changes, in the aggregate and determined cumulatively since March 23, 2010, result in the coverage under the plan (or policy) being substantially different than the coverage that was provided on March 23, 2010. Whether or not there has been a substantial change is a facts and circumstances determination.

Examples illustrate the operation of the rules for grandfathered health plans. The Departments request comments regarding the rules for grandfather health plans, including the impact of the provisions on plans and issuers that made changes to plan terms after March 23,

2010 but prior to issuance of these interim final regulations as well as the impact on plans that made changes to plan terms after March 23, 2010 pursuant to a contract entered into prior to that date].

Comment [b2]: For discussion.

I. Individual Market and Non-Federal Governmental Plan Reforms

1. References to the Public Health Service Act

Conforming changes to references to sections of Title XXVII of the PHS Act are made throughout Parts 144 and 146 to reflect the renumbering of certain sections by the Affordable Care Act.

2. Definitions (45 CFR 144.103)

These interim final regulations define “policy year” as the 12-month period that is designated in the policy documents of individual health insurance coverage. If the policy document does not designate a policy year (or no such document exists), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year. The Affordable Care Act uses the term “plan year” in referring to the period of coverage in both the individual and group health insurance markets. The term “plan year,” however, is generally recognized as having only relevance in the group health insurance market. Accordingly, these interim final regulations substitute the term “policy year” for “plan year” in defining the period of coverage in the individual health insurance market.

These interim final regulations revise the definition of “preexisting condition exclusion” to clarify that the denial of an application for coverage because of a preexisting condition in the individual health insurance market is a preexisting condition exclusion. This definition at 45 CFR 144.103 is cross-referenced in both 45 CFR 146.111(a)(1) and 45 CFR 147.2704, and it

applies in both the group and individual health insurance markets, and also to entities that provide coverage to Federally eligible individuals.

3. Treatment of Non-Federal Governmental Plans (45 CFR 146.180)

The Affordable Care Act made numerous changes to Title XXVII of the PHS Act, including to section 2721(b)(2), which permitted the sponsor of a self-funded non-Federal governmental plan, as defined in 45 CFR 144.103, to elect to exempt the plan from certain requirements of Title XXVII of the PHS Act. This is referred to herein as the “opt-out provision.” Section 1001(4) of the Affordable Care Act re-designated section 2721 as section 2735. Section 1562(b)(12) of the Affordable Care Act amended section 1001(4) by re-designating section 2735(b)(2) as section 2722(a)(2).

Additionally, section 1562(a)(2) of the Affordable Care Act further amended the opt-out provision in §2722 by adding a new subparagraph (a)(2)(E), which prohibits a sponsor of a self-funded non-Federal governmental plan from electing to exempt the plan from the Subparts I and II in Part A of the revised Title XXVII. Subpart I (“General Reform”) contains the provisions of the original Subpart 1 of Part A of title XXVII of the PHS Act. The requirements in the original Subpart 1 included limitations on preexisting condition exclusion periods, special enrollment periods and prohibitions against discriminating against individual participants and beneficiaries based on health status. Because of the prohibition in PHS Act section 2722(a)(2)(E), self-funded non-Federal governmental plans can no longer elect to be exempted from these provisions in Subpart I starting with plan years beginning on or after September 23, 2010.

Section 1001(2) of the Affordable Care Act redesignated sections 2704 through 2707 (which respectively set forth the provisions of the Newborns’ and Mothers’ Health Protection Act of 1996, the Mental Health Parity Act of 1996 (as amended by the Mental Health Parity and

Addiction Equity Act (2008)), the Women's Health and Cancer Rights Act of 1998, and Michelle's Law (2008)) as sections 2725 through 2728, respectively, which are contained in a revised Subpart 2, "Exclusion of Plans; Enforcement; Preemption." A sponsor of a self-funded non-Federal governmental plan may continue to elect to exempt its plan from the requirements of Subpart 2 (which is separate from Subpart II) of Part A of Title XXVII since the prohibition in section 2722(a)(2)(E) does not reference Subpart 2.

Section 1004 of the Affordable Care Act provides, in pertinent part, that the amendments made by section 1001 are "effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act[.]" The Affordable Care Act was enacted on March 23, 2010. Therefore, section 1001, as amended by section 1562(a) and (b)(12), is effective for group health plan years beginning on or after September 23, 2010. The Affordable Care Act makes no exception for plan years beginning on or after September 23, 2010 that are governed by a previously ratified collective bargaining agreement under which the plan sponsor has elected to exempt the self-funded plan from one or more requirements of Subpart 1. The grandfathering provision in section 1251(d) of the Affordable Care Act only applies to insured collectively bargained plans. Accordingly, without regard to a collective bargaining agreement, a sponsor of a self-funded non-Federal governmental plan that commences a new plan year on or after September 23, 2010 can no longer elect to exempt the plan from requirements of Subpart 1. An example in these interim final regulations illustrates this.

Section 146.180 is being revised to reflect changes made by the Affordable Care Act, to add conforming changes and to make certain additional changes unrelated to the Affordable Care Act, such as updating the address to which an opt-out election should be submitted, updating an example to reflect more recent dates, and removing outdated text.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of subtitle K of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act 2701 through 2728 and the incorporation of them into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

These rules are being adopted on an interim final basis because the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process is completed. The statutory requirements implemented in these interim final regulations were enacted on March 23, 2010, and apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Yet, the requirements in these regulations require significant lead time in order to implement.

For example, in the case of the requirement under PHS Act section 2714 to allow dependent children to enroll in a group health plan until they are 26, these interim final regulations require that an enrollment period be provided for no later than the first day this requirement takes effect. Preparations presumably would have to be made to put such an enrollment process in place. In the case of preventive health services that must be provided under section PHS Act section 2713, if the recommendation or guideline requiring coverage of the service was issued before September 23, 2009, group health plans and health insurance issuers have to be prepared to provide coverage of the preventive services by as early as the first plan or policy year beginning on or after September 23, 2010. With respect to all the changes that would be required to be made under these interim final regulations, whether adding coverage of children with a preexisting condition under PHS Act section 2704, or eliminating lifetime limits under PHS Act section 2711, group health plans and health insurance issuers have to be able to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits, and these premiums and plan or policy changes would have to receive necessary approvals in advance of the plan or policy year in question.

For the foregoing reasons, the Departments have determined that it is essential to provide certainty about what will be required of group health plans and health insurance issuers under the statutory requirements implemented in these final regulations as far in advance of September 23, 2010 as possible. This makes it impracticable to engage in full notice and comment rulemaking before putting regulations into effect, and in the public interest to do so through interim final regulations under which the public will have an opportunity for comment, but that opportunity will not delay putting rules in effect (a delay that could possibly last past September 23, 2010).

Having a binding rule in effect is critical to ensuring that individuals entitled to the new protections being implemented have these protections uniformly applied. Even if a notice of proposed rulemaking were issued, it would not be binding, and different group health plans or health insurance issuers could interpret the statutory language in different ways. It therefore is in the public interest that these interim final regulations be in effect and apply when the statutory protections being implemented apply.

IV. Economic Impact and Paperwork Burden

[insert new RIA]

V. Statutory Authority

The Department of the Treasury temporary and final regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104-191, 110 Stat. 1936; sec. 401(b), Public Law 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110-343, 122 Stat. 3765; Public Law 110-460, 122 Stat. 5123; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

**PART 2590—RULES AND REGULATIONS FOR HEALTH INSURANCE
PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS**

1. The authority citation for Part 2590 is revised to read as follows:

Authority:

Subpart B—Other Requirements

2. Section 2590.701-2 is amended by revising the definition of preexisting condition exclusion to read as follows:

§ 2590.701-2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or

group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

3. Section 2590.701-3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 2590.701-2 of this Part.

* * * * *

4. Section 2590.715 is added to Subpart C to read as follows:

§ 2590.715-2704 Prohibition of preexisting condition exclusions.

(a) In general. (1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701-2 of this Part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage due to the fact that a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition. (The denial of an application for coverage based on a preexisting condition exclusion also violates PHS Act section 2702 (guaranteed availability of coverage) and PHS Act section 2705 (prohibition against discrimination based on health status) for policy years beginning on or after January 1, 2014.)

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child into the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma beginning on January 1, 2011, regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13 year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13 year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13 year-old child.

§ 2590.715-2711 No lifetime or annual limits.

(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may establish, for any individual, an annual limit on the dollar

amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining if an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(e) Enrollment rights for individuals previously subject to lifetime limits. See § 2590.715-2800 of this Part for rules requiring that an enrollment opportunity be given to certain individuals who have reached a lifetime limit on the dollar value of all benefits before the date that the requirements of this section apply.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2712 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage

under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission.

(3) The rules of this paragraph (a) are illustrated by the following example:

Example. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A was treated for acne six years ago. A is later diagnosed

with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's prior treatment for acne, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example, the plan cannot rescind A's coverage because A's failure to disclose the prior treatment for acne was not fraudulent or an intentional misrepresentation of material fact.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage, including the requirement under PHS Act section 2719(a)(1)(C), which requires a plan or an issuer to allow an enrollee to continue coverage pending the outcome of an appeal of a coverage or claim determination.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2713 Coverage of preventive health services.

(a) In general—(1) Beginning at the time described in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements with respect to those items or services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

(2) Nothing in this paragraph (a) prohibits a plan or issuer from providing coverage for services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for services that are not recommended by that task force or that advisory committee, or under those guidelines.

(b) Timing—(1) In general. A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that

begin on or after the later of September 23, 2010, or one year after the date the recommendation or guideline is issued.

(2) Changes in recommendations or guidelines. A plan or issuer is not required under this section to provide coverage for any recommendation or guideline after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such recommendation or guideline, including PHS Act section 2715(d)(4), which requires a plan or an issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) Recommendations not current. For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2714 Eligibility of children until at least age 26.

(a) In general. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, that makes available dependent coverage for children must allow such coverage for children until attainment of 26 years of age.

(b) Restrictions on plan definition of dependent. With respect to children who have not attained age 26, a plan or issuer may not define dependent for purposes of

eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant (in the individual market, the primary subscriber). Thus, for example, a plan or issuer may not deny or restrict coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency, residency with the participant (in the individual market, with the primary subscriber), student status, employment, or any combination of those factors. In addition, a plan or issuer may not deny or restrict coverage for a child based on eligibility for other coverage, except that paragraph (g) of this section provides a special rule for plan years beginning before January 1, 2014 for grandfathered health plans that are group health plans. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may mandate coverage for certain children.)

(c) Coverage of grandchildren not required. Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) Uniformity irrespective of age. The terms of the plan or health insurance coverage providing dependent coverage for children cannot vary based on age (except for children who are age 26 or older).

(e) Examples. The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) Conclusion. In this Example 1, the plan violates the requirements of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) Facts. A group health plan offers a choice among the following tiers of health coverage: self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage to children who have not attained age 26.

(ii) Conclusion. In this Example 2, the plan does not violate the requirement of paragraph (d) of this section that the terms of coverage for dependent children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any dependent child.

Example 3. (i) Facts. A group health plan offers two benefit packages -- an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) Conclusion. In this Example 3, the plan violates the requirements of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

(f) Enrollment rights for individuals who previously lost dependent status. See § 2590.715-2800 of this Part for rules requiring that an enrollment opportunity be given to certain children under age 26 who are not granted coverage before the date that the requirements of this section apply.

(g) Special rule for grandfathered group health plans. For plan years beginning before January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act may exclude an adult child who has not attained age 26 from coverage only if the adult child is eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a group health plan of a parent.

(h) Applicability date. The provisions of this section apply for plan years (in

the individual market, policy years) beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2716 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code that apply to self-insured medical reimbursement plans (prohibiting discrimination in favor of highly compensated individuals as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-insured plan) under this section as if the group health plan were a self-insured medical reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-2801 of this Part for determining the application of this section to grandfathered health plans.

§ 2590.715-2800 Transitional rules for individuals whose coverage ended due to reaching a lifetime limit or a dependent eligibility threshold.

(a) Applicability. The relief provided in the transitional rules of this section applies with respect to any individual who becomes eligible for coverage under a group health plan or group or individual health insurance coverage upon the effective date of a provision of subtitle A or subtitle C of title I of the Patient Protection and Affordable Care Act or the regulations thereunder and:

(1) Whose coverage under a group health plan or group or individual health insurance coverage ended by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which is no longer permissible under § 2590.715-2711 of this Part); or

(2) Whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or group or individual health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26 (which is no longer permissible under § 2590.715-2714 of this Part).

(b) Opportunity to enroll required—(1) For an individual described in paragraph (a) of this section, if the group health plan, or the group or individual health insurance coverage, in which the individual is eligible to enroll is the plan or coverage in which the

individual's coverage ended for the reasons described in paragraphs (a)(1) or (a)(2) of this section, and if the plan, or the issuer of such coverage, is subject to the requirements of § 2590.715-2711 or § 2590.715-2714 of this Part, the plan or issuer is required to give the individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This opportunity must be presented not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(2) The written notice must include a statement that individuals who lost coverage by reason of reaching a lifetime limit, or by reason of ceasing to be a dependent before attainment of age 26, as applicable, are eligible to enroll in the plan or coverage. The written notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent.

(3) In the case of an individual who enrolls under this paragraph (b), coverage must take effect not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(c) Treatment of enrollees in a group health plan. For purposes of this Part, any individual enrolling in a group health plan pursuant to paragraph (b) of this section must be treated as if the individual were a special enrollee, as provided under the rules of § 2590.701-6(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit or cessation of dependent status. For this purpose, any

difference in benefits or cost-sharing requirements constitutes a different benefit package.

The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit or cessation of dependent status.

(d) Examples. The rules of this section are illustrated by the following examples:

Example 1. (i) Facts. Employer X maintains a group health plan with a calendar year plan year. For the 2010 plan year, the group health plan imposes a \$1 million lifetime limit. Individual A is an employee of X and a participant in X's group health plan. On April 15, 2010, A incurs claims under the group health plan that, together with all previous claims, exceed the lifetime limit. On November 1, 2010, X's group health plan provides written notice to A that individuals who lost coverage by reason of reaching a lifetime limit are eligible to enroll in the plan or coverage during the plan's open season for the 2011 plan year, which runs from November 15, 2010 to December 15, 2010. Enrollment will become effective on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this section that it present an enrollment opportunity to A.

Example 2. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. For the 2010 plan year, the group health plan allows children of employees to be covered under the plan until age 19, or until age 23 for children who are full-time students. Individual B, an employee of Y, and Individual C, B's child and a full-time student, were enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, C turns 23 years old and loses dependent coverage under Y's plan. On or before January 1, 2011, Y's group health plan gives B written notice that individuals who lost coverage by reason of ceasing to be a dependent before attainment of age 26 are eligible to enroll in the plan or coverage, and that individuals may request enrollment for such dependents through February 14, with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 2, the plan has complied with the requirements of this section that it present an enrollment opportunity to C.

Example 3. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan allows children of employees to be covered under the plan until age 22. Individual D, an employee of Z, and Individual E, D's child, are enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E turns 22 years old and ceases to be eligible as a dependent under Z's plan and loses coverage. D drops coverage but remains an employee of Z before October 1, 2010.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 4. (i) Facts. Same facts as Example 3, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 4, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 5. (i) Facts. Same facts as Example 3, except that E elected COBRA continuation coverage.

(ii) Conclusion. In this Example 5, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll other than as a COBRA qualified beneficiary (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 6. (i) Facts. Employer X maintains a group health plan with a calendar year plan year. Prior to 2011, the plan allows children of employees to be covered under the plan until the child attains age 22. During the 2009 plan year, an individual with a 22-year old child joins the plan; the child is denied coverage because the child is 22.

(ii) Conclusion. In this Example 6, notwithstanding that the child was not previously covered under the plan, the plan must provide the child, not later than January 1, 2011, an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than January 1, 2011.

§ 2590.715-2801 Preservation of right to maintain existing coverage.

(a) Definition of grandfathered health plan coverage—(1) In general—(i)

Coverage provided by a group health plan, or a group or individual health insurance issuer, in which an individual was enrolled on March 23, 2010 is grandfathered health plan coverage (for as long as it maintains that status under paragraph (g) of this section), regardless of whether the individual renews the coverage after March 23, 2010. For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan.

(ii) If, on March 23, 2010, no individuals in a group health plan were enrolled in a particular policy, certificate, or contract of insurance, that policy, certificate, or contract of insurance is not a grandfathered health plan with respect to the individuals in the group health plan.

(2) Documentation of plan or policy terms on March 23, 2010. To maintain status as a grandfathered health plan, a group health plan, or group or individual health insurance coverage, must –

(i) Maintain records documenting the plan or policy terms in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(ii) Make such records available for examination.

(3) Family members enrolling after March 23, 2010. Grandfathered health plan coverage includes coverage of family members of an individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(b) Allowance for new employees to join current plan. A group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010.

(c) General grandfathering rule—(1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those

amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709, 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. In addition, the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it applies to annual limits, do not apply to grandfathered health plans that are individual health insurance coverage.

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) Provisions applicable to all grandfathered health plans. The provisions of PHS Act section 2711 insofar as it applies to lifetime limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(e) Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health coverage—(1) The provisions of PHS Act section 2704 as it applies to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to

grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent.

(f) Effect on collectively-bargained plans. In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage which amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of paragraph (g) of this section (comparing the terms of the coverage after the date the last collective bargaining

agreement terminates with the terms of the coverage that were in effect on March 23, 2010).

(g) Maintenance of grandfather status—(1) Changes causing loss of grandfather status—(i) Any of the following changes in the terms of a grandfathered health plan will cause the plan or coverage to cease to be a grandfathered health plan:

(A) Any increase in a fixed-amount cost-sharing requirement (e.g., deductible, copayment, or out-of-pocket limit), determined as of the effective date of the increase, if the total increase in such requirement measured from March 23, 2010 exceeds a percentage equal to the sum of:

(1) 15 percent; and

(2) The increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI-U) (unadjusted) published by the Department of Labor using the 1982 – 1984 base of 100, expressed as a percentage. For this purpose, the increase in the overall medical care component is computed by dividing the index amount for any month in the twelve months before the new change is to take effect by 387.142 (the overall medical care component of the CPI-U (unadjusted) published by the Department of Labor for March 2010, using the 1982 – 1984 base of 100), subtracting one from that quotient, and then, to express as a percentage, multiplying by 100.

(B) Any increase in a percentage cost-sharing requirement (such as increasing an individual's 20 percent coinsurance requirement to 25 percent).

(C) The elimination of all or substantially all benefits to diagnose or treat a particular condition.

(ii) In the case of a change not described in paragraph (g)(1)(i) or (g)(2) of this section, such as an elimination of less than all or substantially all benefits to diagnose or treat a particular condition, the rules of paragraph (g)(3) of this section apply.

(2) Safe harbor: changes that do not affect grandfather status. The following changes in the terms of a grandfathered health plan do not change the status of the plan or coverage as a grandfathered health plan:

(i) Any changes in the premium that, in the individual market, a health insurance issuer charges an individual for coverage.

(ii) Any changes in the premium that, in the group market, a health insurance issuer charges an employer for coverage (or to the extent that a multiemployer plan is self-insured, changes in the total amount that an employer is required to pay for coverage).

(iii) Any changes in the amount that an employer or employee organization contributes toward coverage (whether insured or self-insured).

(iv) Any changes in the amount that a participant is required to contribute towards coverage under a group health plan (whether insured or self-insured).

(v) Any changes to comply with Federal or State legal requirements that apply to the grandfathered health plan.

(vi) Any changes to voluntarily comply with provisions of the Patient Protection and Affordable Care Act that do not apply to the grandfathered health plan.

(vii) For the first plan year beginning on or after September 23, 2010 (in the individual market, the first policy year), replacement of a lifetime limit with an annual limit as permitted by § 2590.715-2711 of this Part.

(viii) Any decrease in cost-sharing for the individual (including the establishment of an out-of-pocket limit) or an increase in covered benefits (such as a new covered item or service).

(ix) Any increase in a fixed-amount cost-sharing requirement (e.g., deductible, copayment, or out-of-pocket limit), determined as of the effective date of the increase, if the total increase in such requirement measured from March 23, 2010 does not exceed a percentage equal to the sum of:

(A) 15 percent; and

(B) The increase since March 2010 in the overall medical care component of the CPI-U (unadjusted) published by the Department of Labor, using the 1982 – 1984 base of 100 expressed as a percentage. For this purpose, the increase is computed in the manner described in paragraph (g)(1)(i)(A) of this section.

(3) Other changes. Changes other than those described in paragraph (g)(1)(i) or (g)(2) of this section do not cause a plan (in the individual market, policy) to lose grandfather status, unless one or more of such changes (considered in the aggregate and determined cumulatively since March 23, 2010) result in the coverage under the plan (or policy) being substantially different than the coverage that was provided on March 23, 2010.

(h) The rules of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan not maintained pursuant to a collective bargaining agreement provides coverage through a group health insurance policy from Issuer X on March 23, 2010. For the plan year beginning January 1, 2012, the plan enters into a new policy with Issuer Z.

(ii) Conclusion. In this Example 1, for the plan year beginning January 1, 2012, the group health insurance coverage issued by Z is not a grandfathered health plan under

the rules of paragraph (a)(1)(ii) of this section because the policy issued by Z did not provide coverage on March 23, 2010.

Example 2. (i) Facts. A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option F is a self-insured option. Options G and H are insured options. Beginning July 1, 2013, the plan replaces the issuer for Option H with a new issuer.

(ii) Conclusion. In this Example 2, the coverage under Option H is not grandfathered health insurance coverage as of July 1, 2013, consistent with the rule in paragraph (a)(1)(ii) of this section. Whether the coverage under Options F and G is grandfathered health coverage is determined under the rules of paragraph (g) of this section.

Example 3. (i) Facts. A group health plan maintained pursuant to a collective bargaining agreement provides coverage through a group health insurance policy from Issuer W on March 23, 2010. The group health plan enters into a new group health insurance policy with Issuer Y for the plan year starting on January 1, 2011. The collective bargaining agreement has not been amended and will not expire before December 31, 2011.

(ii) Conclusion. In this Example 3, the group health plan, and the group health insurance policy provided by Y, remains a grandfathered health plan with respect to existing employees and new employees and their families because the coverage is maintained pursuant to a collective bargaining agreement ratified prior to March 23, 2010 that has not terminated.

Example 4. (i) Facts. Same facts as Example 3, except the coverage with W is renewed under a new collective bargaining agreement effective January 1, 2012, with the only changes being changes described in paragraph (g)(2) of this section.

(ii) Conclusion. In this Example 4, the group health plan remains a grandfathered health plan pursuant to the rules of this section. Moreover, the group health insurance policy provided by W remains a grandfathered health plan under the rules of paragraph (g) of this section.

Example 5. (i) Facts. On March 23, 2010, a grandfathered health plan has a copayment requirement of \$30 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$35. Within the 12-month period before the \$35 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 415.

(ii) Conclusion. In this Example 5, the increase in the copayment from \$30 to \$35, expressed as a percentage is 16.67% ($35 \div 30 = 1.1667$; $1.1667 - 1 = 0.1667$; $0.1667 = 16.67\%$). The percentage increase in the overall medical care component of the CPI-U (unadjusted) from March 2010 is 7.20% ($415 \div 387.142 = 1.0720$; $1.0720 - 1 = 0.0720$;

0.0720 = 7.20%). The maximum percentage increase that would be permitted under paragraph (g)(1)(i)(A) is 22.20% ($15\% + 7.20\% = 22.20\%$). Because 16.67% does not exceed 22.20%, the change in the copayment requirement at that time does not cause the grandfathered health plan to lose grandfathered status.

From: [Mayhew, James A. \(CMS/CPC\)](#)
To: [Drobac, Krista \(HHS/OCIIO\)](#)
Subject: RE: Meeting Request on Annual Dollar Limits/Limited Medical Benefit Plans
Date: Thursday, May 06, 2010 9:22:00 AM

These people get the issue- they're referring to restricted annual limits, unlike the prior e-mail which referred to a prohibition on annual limits.

Is it OK for me to forward this to my colleagues at Labor and Treasury?

From: Drobac, Krista (HHS/OCIIO)
Sent: Thursday, May 06, 2010 9:18 AM
To: Mayhew, James A. (CMS/CPC)
Subject: FW: Meeting Request on Annual Dollar Limits/Limited Medical Benefit Plans

From: Joel Kopperud [<mailto:Joel.Kopperud@ciab.com>]
Sent: Wednesday, May 05, 2010 10:30 AM
To: Drobac, Krista (HHS/OCIIO)
Cc: Scott Sinder; Joel Wood; Nicole Allen
Subject: Meeting Request on Annual Dollar Limits/Limited Medical Benefit Plans

Hi Krista,

We talked briefly this morning and yesterday, but I'd like to introduce myself more formally. My name is Joel Kopperud and I'm the Director of Government Affairs for the Council of Insurance Agents and Brokers. I'm writing to request a meeting with you to discuss Limited Medical Benefit Plans and the impact of forthcoming HHS regulations regarding annual dollar limits.

You may already be aware of the issue—we are concerned that Limited Medical Benefit Plans could cease to exist on September 23rd, jeopardizing coverage for over a million individuals until the exchanges are built in 2014. My understanding is that prior to 2014, PPACA says the Secretary is to establish annual dollar limits until the exchanges are built, and our fear is that if the limits are too high or don't provide an exception for Limited Medical Benefit Plans, employees covered under these plans will lose their coverage during the transition period. The plans generally serve lower-wage, seasonal, part-time and temporary workers.

I suspect this would be an unintended result, but would greatly appreciate some of your time to discuss the issue with me, my colleague Joel Wood and our General Counsel Scott Sinder of Steptoe and Johnson. We represent commercial insurance and employee benefits brokers. Our members annually place over 80 percent of all commercial property/casualty insurance in the U.S. and are leaders in administering employee benefits programs.

I know you're slammed right now and am very grateful for any time you can offer. Given the timeliness of the issue, something in the next week or so would be ideal, but I understand limited schedules-- so we'll keep our calendars flexible.

Thank you!

Joel

Joel T. Kopperud
Director of Government Relations
The Council of Insurance Agents & Brokers
701 Pennsylvania Avenue NW Suite 750
Washington, DC 20004
202.662.4311 Direct
202.783.4400 Main
202.783-4410 Fax
www.ciab.com



The Council Calendar

Wholesale Insurance Leadership Forum – May 10-12, 2010

Employee Benefits Leadership Forum- June 1-4, 2010

CFO Workshop - June 16 - 18, 2010

Leadership Development Conference - June 16 - 18, 2010

Insurance Leadership Forum - October 2-6, 2010

www.ciab.com/meetings

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To: [Mayhew, James A. \(CMS/CPC\)](#)
Subject: FW: Meeting Request on Annual Dollar Limits/Limited Medical Benefit Plans
Date: Thursday, May 06, 2010 9:18:23 AM

From: Joel Kopperud [mailto:Joel.Kopperud@ciab.com]
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To: Drobac, Krista (HHS/OCIIO)
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Subject: FW: Meeting Request on Annual Dollar Limits/Limited Medical Benefit Plans
Date: Thursday, May 06, 2010 9:18:23 AM

From: Joel Kopperud [mailto:Joel.Kopperud@ciab.com]
Sent: Wednesday, May 05, 2010 10:30 AM
To: Drobac, Krista (HHS/OCIIO)
Cc: Scott Sinder; Joel Wood; Nicole Allen
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From: [Mayhew, James A. \(CMS/CPC\)](#)
To: [Drobac, Krista \(HHS/OCIIO\)](#)
Subject: RE: Hill Q - Annual Limits
Date: Thursday, May 06, 2010 9:10:00 AM

Krista-

The statute only prohibits lifetime limits for plan or policy years beginning on or after September 23, 2010. Annual limits will be permissible on a restricted basis for group health plans and individual health insurance plans until January 1, 2014. The regulations will discuss in some detail the restrictions on annual limits.

For individual health insurance plans that were in existence on March 23, 2010, the existing annual limits will be permitted to remain the same for as long as the individual keeps the policy and as long as there is no substantial change to the policy.

Let me know if this is helpful.

Jim

From: Drobac, Krista (HHS/OCIIO)
Sent: Thursday, May 06, 2010 8:47 AM
To: Mayhew, James A. (CMS/CPC)
Subject: FW: Hill Q - Annual Limits

From: Fitzgerald, Erin (HHS/ASL)
Sent: Wednesday, May 05, 2010 11:16 PM
To: Drobac, Krista (HHS/OCIIO)
Cc: Engel, Elizabeth (HHS/ASL); Taylor, Bridgett (HHS/ASL); Kidwell, Lauren (HHS/ASL)
Subject: Hill Q - Annual Limits

Hey Krista - offices are hearing a lot of concerns from businesses in their state as to how the "no lifetime/ annual limits" provision will affect the businesses' premiums and/or the insurance options they have. Here's one specific question we have. Can you help answer?

Thanks,
Erin

Background: Rep. Larsen and Senator Cardin are concerned that the prohibition on annual benefit limits will force out group limited benefit plans. These cheaper plans offer very limited benefits, and Larsen/Cardin agree that we don't want people in plans like that in the long term. However, 1.5 million people currently have limited benefit plans, and they are concerned about what will happen to these 1.5 million people in the gap between when this provision takes effect later this year, and when the exchanges are up and running in 2014. Cardin's folks are also worried about the insurers offering these plans will go out of business. They are concerned that because they have mostly healthy people that they won't be able to meet the MLR (duh), they want to know how we will handle this.

Q: How does HHS plan to address the possibility that the prohibition of annual benefit limits will force out group limited benefit plans? Obviously we can't pre-judge the regs and if any specific groups of people will be addressed specifically, but is there any info we can share?

From: [Drobac, Krista \(HHS/OCIIO\)](#)
To: [Mayhew, James A. \(CMS/CPC\)](#)
Subject: FW: Hill Q - Annual Limits
Date: Thursday, May 06, 2010 8:46:39 AM

From: Fitzgerald, Erin (HHS/ASL)
Sent: Wednesday, May 05, 2010 11:16 PM
To: Drobac, Krista (HHS/OCIIO)
Cc: Engel, Elizabeth (HHS/ASL); Taylor, Bridgett (HHS/ASL); Kidwell, Lauren (HHS/ASL)
Subject: Hill Q - Annual Limits

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[Billing Codes: 4830-01-P; 4510-29-P; 4120-01-P]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 54 and 602

TD

RIN 1545-~~BJ61XXXX~~

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-XXXX

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

OCIO-XXXX-IFC

45 CFR Part 147

RIN XXXX-XXXX

Interim Final Rules ~~for Group Health Plans and Health Insurance Issuers~~ under the Patient Protection and Affordable Care Act Regarding Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, No Discrimination in Favor of the Highly Compensated, Patient Protections, and Non-Federal Governmental Plans

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, no discrimination in favor of highly compensated individuals, patient protections, and non-federal governmental plans.

DATES: Effective date. These interim final regulations are effective on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Comment date. Comments are due on or before **[INSERT DATE 90 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

Applicability date. These interim final regulations generally apply to group health plans and group health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**. These interim final regulations generally apply to individual health insurance issuers on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines.

No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB42, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Email: [E-OHPSCA\[XXXX\].EBSA@dol.gov](mailto:E-OHPSCA[XXXX].EBSA@dol.gov).

- Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: RIN 1210-AB42.

Comments received by the Department of Labor will be posted without change to www.regulations.gov and www.dol.gov/ebsa, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIO-9991-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.
2. By regular mail. You may mail written comments to the following address ONLY:
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services,

Attention: OCIIIO-9991-IFC,

P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services,

Attention: OCIIIO-9991-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to

leave their comments in the OCIIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the

headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-~~1203998412~~-10, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: CC:PA:LPD:PR (REG-1~~203998412~~-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-1~~203998412~~-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786-1565.

CUSTOMER SERVICE INFORMATION: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's website (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for

consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp) and information on health reform can be found at <http://www.healthreform.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of part A of title XXVII of the PHS Act applicable under ERISA and the Code to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if those provisions of the PHS Act were included in ERISA and the Code. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The

¹ The term “group health plan” is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term “health plan”, as used in other provisions of title I of the Affordable Care Act. The term “health plan” does not include self-insured group health plans.

preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of the Affordable Care Act are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers stricter requirements than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations implementing the revised PHS Act sections 2701 through 2719A in several phases. The first publication in this series was a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). The second publication was interim final regulations implementing PHS Act section 2714 (requiring dependent coverage of children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third publication was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on ~~June~~^{May} XX, 2010 (75 FR XXXXX). These interim final regulations are being published to implement PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), 2716 (prohibiting discrimination in favor of highly compensated individuals), 2719A (regarding patient protections), and 2722 (regarding the application of the Affordable Care Act provisions to

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

nonfederal governmental plans). PHS Act section 2704 generally is effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014. However, with respect to enrollees, including applicants for enrollment, who are under 19 years of age, PHS Act section 2704 is effective for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.³ The rest of these provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

II. Overview of the Regulations:

A. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815-2704, 29 CFR 2590.715-2704, 45 CFR 147.108)

Section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA⁴ rules relating to preexisting condition exclusions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under certain circumstances. The Affordable Care Act provision prohibits any preexisting condition exclusions imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1,

³ Section 1255 of the Affordable Care Act. See also section 10103(e)-(f) of the Affordable Care Act.

⁴ HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

HIPAA generally defines a preexisting condition exclusion⁵ as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

For group health plans and group health insurance issuers, a denial of coverage of an individual based on a preexisting condition exclusion also violates the HIPAA rules prohibiting discrimination based on a health factor.⁶ Beginning on January 1, 2014, a denial of coverage of an individual based on a preexisting condition would also violate more than one provision in the individual market: the prohibition against preexisting condition exclusions, the guaranteed availability requirement, and the prohibition against discrimination based on health status. ~~Of course, if~~ an individual was denied coverage beginning in 2014 on a ground ~~other than unrelated~~ to the existence of a preexisting condition or a health factor, the denial would ~~only still~~ violate the right to guaranteed availability.

The protections in the new PHS Act section 2704 generally apply to plan years (in the individual market, policy years) beginning on or after January 1, 2014. The Affordable Care Act provides, however, that these protections apply with respect to enrollees under age 19 for

⁵ Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1); after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1). See also ERISA section 701(b)(1) and Code section 9801(b)(1).

⁶ 26 CFR 54.9802-1; 29 CFR 2590.702; 45 CFR 146.121.

plan years (in the individual market, policy years) beginning on or after September 23, 2010. An enrollee under age 19 thus could not be denied benefits based on a preexisting condition. In order for an individual to receive the same protection that applies in the case of such an enrollee, the individual similarly could not be denied benefits (in whole or part) based on a preexisting condition. Thus, for plan years (in the individual market, for policy years) beginning on or after September 23, 2010, PHS Act section 2704 protects individuals under age 19 with a preexisting condition from being denied coverage under a plan (in whole or part) based on the preexisting condition.

These interim final regulations do not change the HIPAA rule that a plan's or issuer's exclusion of benefits for a condition from the plan or policy regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. This point is still relevant for these interim final regulations and is illustrated with examples in the HIPAA regulations on preexisting condition exclusions.⁷ (Other requirements of Federal or State law, however, may prohibit certain benefit exclusions.)

The interim final regulations under PHS Act section 2714 (relating to the continuation of dependent coverage until [a child turns](#) age 26)⁷ (75 FR 27122, May 13, 2010) provide that the terms of a plan or policy for dependent coverage cannot vary based on the age of a child, except for children age 26 or older. These interim final regulations amend those regulations to clarify that, for plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or policy may impose a preexisting condition exclusion (consistent with the rules of 26 CFR 54.9801-3, 29 CFR 2590.701-3, and 45 CFR 146.111) on children who are age 19 or older even though this is prohibited with respect to children under age 19.

⁷ See Examples 6, 7, and 8 in 26 CFR 54.9801-3(a)(1)(ii), 29 CFR 701-3(a)(1)(ii), 45 CFR 146.111(a)(1)(ii).

Application to grandfathered health plans. Under the statute and these interim final regulations, a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704. See 26 CFR 54.9815-1251^T, 29 CFR 2590.715-1251, and 45 CFR 147.140 regarding status as a grandfathered health plan.

B. PHS Act Section 2711, Lifetime and Annual Limits (26 CFR 54.9815-2711^T, 29 CFR 2590.715-2711, 45 CFR 147.???)

Section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits. However, these interim final regulations provide that the annual limit rules do not apply to health flexible spending arrangements.⁸

The statute also allows “restricted annual limits” with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. In addition, the statute provides that, with respect to benefits that are not essential health benefits, a plan or issuer may impose annual or lifetime per individual limits on specific covered benefits. Rather than provide a definition of “essential health benefits,” these interim final regulations cross-reference section 1302(b) of the Affordable Care Act and applicable regulations.⁹

These interim final regulations clarify that the prohibition under PHS Act section 2711 does not prevent a plan or issuer from excluding all benefits for a condition, but if any benefits

⁸ Section 9005 of the Affordable Care Act specifically limits the annual amount of salary reduction contributions for health flexible spending arrangements.

⁹ Regulations under section 1302(b) of the Affordable Care Act have not yet been issued.

are provided for a condition, then the requirements of the rule apply. Therefore, an exclusion of all benefits for a condition is not considered to be an annual or lifetime dollar limit.

The statute and these interim final regulations provide that for plan years (in the individual market, policy years) beginning before January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may ~~only~~ establish a restricted annual limit on the dollar value of essential health benefits. The statute provides that in defining the term “restricted annual limit,” the Departments “ensure that access to needed services is made available with a minimal impact on premiums.”¹⁰

In establishing the restricted annual limit, the Departments considered several factors: (1) the current use of annual limits in the group and individual market; (2) the average premium impact of imposing different annual limits on the individual, small group, and large group markets; (3) the number of individuals who will continue to have annual medical expenses that exceed an annual limit; and (4) the possibility that a plan or issuer would switch to an annual limit when lifetime limits are prohibited.

~~Approximately four percent of large employer plans, eight percent of small employer PPO plans, and 19 percent of individual market plans currently have annual limits. Although available data show that very few health insurance plans impose annual limits, at least half of small group plans and over 75 percent of policies in the individual market impose lifetime limits. The 2009 Kaiser Family Foundation/HRET Survey of Employers found that less than one percent of covered workers had lifetime limits less than \$1 million, 16 percent had limits between \$1 million and \$1.99 million, 43 percent had lifetime limits of \$2 million or more, and 41 percent had no lifetime maximum.¹⁰ Of those enrollees in indemnity plans with lifetime~~

¹⁰ See the Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), at <http://ehbs.kff.org/pdf/2009/7936.pdf>.

~~limits, 63 percent of single enrollees and 44 percent of family enrollees had lifetime maximums less than \$2 million while less than one percent of enrollees in network based arrangements, such as HMOs, PPOs, or high deductible health plans with savings options had lifetime maximums less than \$2 million. While it is possible that those plans with lifetime limits will switch to annual limits prior to the elimination of annual limits in 2014, group health plans and health insurance issuers could use a number of changes to benefit design to mitigate any potential premium increases.~~

Comment [b1]: Can we get rid of this whole paragraph? Cross reference the discussion in the economic analysis that goes over these same statistics?

If not, use cite for the 1st sentence from economic analysis cite to Mercer survey (FN 31 in old draft)

In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, these interim final regulations adopt a three-year phased approach for restricted annual limits. ~~This phased-in approach provides ample opportunity for plans with relatively low annual limits (e.g., \$100,000, \$250,000, or \$500,000) to more gradually make adjustments that might smooth any increase in costs that might result from the increased minimum annual limits under these interim final regulations. The proposed annual limit levels ensure that the vast majority of individuals who may experience high medical costs during the year will continue to have access to coverage. Under~~

~~These interim final regulations, provide the following minimum amounts for annual limits on the dollar value of benefits that are essential health benefits may not be less than the following amounts~~ for plan years (in the individual market, policy years) beginning before January 1, 2014:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, \$750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, \$1.25 million; and

- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2 million.

As these are minimums for plan years (in the individual market, policy years) beginning before 2014, plans or issuers may always use higher annual limits or impose no limits. Plans and policies with plan or policy years that begin between September 23 and December 31 have more than one plan or policy year under which the \$2 million minimum annual limit is available; however, a plan or policy generally may not impose an annual limit for a plan year beginning after December 31, 2013.

The minimum annual limits for plan or policy years beginning before 2014 apply on an individual-by-individual basis. Thus, any overall annual dollar limit on benefits applied to families may not operate to deny a covered individual the minimum annual benefits for the plan year (in the individual market, policy year). These interim final regulations clarify that, in applying annual limits for plan years (in the individual market, policy years) beginning before January 1, 2014, the plan (or policy) may only take into account essential health benefits.

Although the restricted annual limits provided in these interim final regulations are designed to ensure, in the vast majority of cases, that individuals would have access to needed services with a minimal impact on premiums, the Departments recognize that for a small minority of plans or health insurance coverage, compliance with the annual limit requirement prescribed in these interim final regulations could have the effect of either denying access to needed services or having more than a minimal impact on premiums. In order to avoid having individuals with such coverage be denied access to needed services or experience more than a minimal impact on premiums, these interim final regulations provide for the Secretary [of HHS] to establish a program under which the requirements relating to annual limits may be waived if

compliance with these interim final regulations will result in a significant decrease in access to benefits or a significant increase in premiums. The Departments request comments on the scope of the program. For example, should both insured and self-insured coverage be eligible for the program? Should certain low-cost benefit plans (sometimes referred to as mini-med plans) or health reimbursement arrangements be eligible? Should the waiver apply to the entire period before January 1, 2014 or be granted on a plan-year-by-plan-year basis?

These interim final regulations provide an enrollment (in the individual market, reinstatement) opportunity for individuals who reached their lifetime limits in a group health plan or health insurance coverage and remain otherwise eligible for the coverage. In the individual market, this reinstatement opportunity does not apply to individuals who reached their lifetime limits in individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in a family policy in the individual market while other family members remain in the coverage. This opportunity must be made available no later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. ~~See discussion of transitional rules in Section H.G. of this preamble.~~

Application to grandfathered health plans. The statute and these interim final regulations relating to the prohibition on lifetime limits apply to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the prohibition on annual limits, including the special rules regarding restricted annual limits for plan years beginning before January 1, 2014, apply to group health plans and group health insurance

coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage.¹¹

C. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815-2712T, 29 CFR 2590.715-2712, 45 CFR 147.???)

PHS Act section 2712 provides rules regarding rescissions¹² of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard applies to all rescissions, whether in the group or individual insurance market, or self-insured coverage. These rules also apply regardless of any contestability period of the plan or issuer.

These interim final regulations include several clarifications regarding the standards for rescission. First, these interim final regulations clarify that the rules of PHS Act section 2712 apply whether the rescission applies to a single individual or an entire group of individuals. Thus, for example, if an issuer attempted to rescind coverage of an entire employer group based

¹¹ Note also that the regulations issued under section 1251 of the Affordable Care Act include a rule relating to retention of status as a grandfathered health plan based on changes to annual limits. Under those regulations, three different situations are addressed. First, a plan or health insurance coverage that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits. Second, a plan or health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010. Third, a plan or health insurance coverage that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

¹² For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission.

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on the actions of an individual within the group, the standards of these interim final regulations would apply. Second, these interim final regulations clarify that the rules of PHS Act section 2712 apply to representations made by the individual or a person seeking coverage on behalf of the individual. Thus, if a plan sponsor seeks coverage from an issuer for an entire employment-based group and makes representations, for example, regarding the prior claims experience of the group, the standards of these interim final regulations would also apply. Finally, PHS Act section 2712 refers to acts or practices that constitute fraud. These interim final regulations clarify that, to the extent that an omission constitutes fraud, that omission would permit the plan or issuer to rescind coverage under this section. An example in these interim final regulations illustrates the application of the rule to misstatements of fact that are inadvertent.

For purposes of these interim final regulations, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission, and neither is a cancellation or discontinuance of coverage that is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

PHS Act section 2712 adds a new advance notice requirement when coverage is rescinded where still permissible. Specifically, the second sentence in section 2712 provides that coverage may not be cancelled unless prior notice is provided, and then only as permitted under PHS Act sections 2702(c) and 2742(b). Under these interim final regulations, even if prior

notice is provided, rescission is only permitted in cases of fraud or an intentional misrepresentation of a material fact as permitted under the cited provisions.¹³ While this reference appears redundant, it is consistent with the first sentence.

These interim final regulations provide that a group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 days advance notice to an individual before coverage may be rescinded.¹⁴ The notice must be provided regardless of whether the rescission is of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group.

These interim final regulations also clarify that other requirements of Federal or State law may apply in connection with a rescission of coverage, including the requirement under PHS Act section 2719(a)(1)(C), which requires a plan or an issuer to allow an enrollee to continue coverage pending the outcome of an appeal of a coverage or claim determination. Regulatory guidance regarding the provisions of PHS Act section 2719 is expected to be issued in the near future.

Application to grandfathered health plans. The rules regarding rescissions and advance notice apply to all grandfathered health plans.

D. PHS Act Section 2716, Prohibiting Discrimination in Favor of Highly Compensated Individuals (26 CFR 54.9815-2716T, 29 CFR 2590.715-2716, 45 CFR 147.???)

¹³ The reference to section 2702(c) appears to be incorrect. After the amendments made by the Affordable Care Act, PHS Act section 2702(c) addresses network requirements for guaranteed availability of coverage. It seems more likely that the intended cross-reference is to new PHS Act section 2703(b), relating to nonrenewal of coverage in the group market, which corresponds to the other cross-reference, in PHS Act section 2742(b), to nonrenewal of coverage in the individual market. Both these provisions contain the fraud and intentional misrepresentation of material fact standard included in the first sentence of section 2712. In order to avoid confusion, these interim final regulations apply the fraud and misrepresentation standard found in sections 2703(b) and 2742(b).

¹⁴ Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

PHS Act section 2716 and these interim final regulations incorporate the nondiscrimination rules of section 105(h) of the Code and apply them to group health plans that are not self-insured plans. Section 105(h) generally prohibits self-insured medical reimbursement plans from discriminating in favor of highly compensated individuals in eligibility classifications or in benefits. Section 105(b) of the Code generally excludes from an employee's income (otherwise subject to federal income taxation) amounts received as reimbursement of medical care expenses for the employee or the employee's spouse, dependents, or children who have not attained age 27 by the end of the taxable year. If a self-insured medical reimbursement plan does not comply with the requirements of section 105(h), the general exclusion from income (and hence, from federal income taxation) under section 105(b) does not apply with respect to highly compensated individuals. Highly compensated individuals are defined in section 105(h).

PHS Act section 2716 and these interim final regulations incorporate the substantive nondiscrimination requirements of Code section 105(h) but not the tax sanctions. An insured group health plan failing to comply with the nondiscrimination requirements of Code section 105(h) is subject to the sanctions and remedies that generally apply for a plan failing to comply with the requirements of chapter 100 of the Code (generally, an excise tax of \$100 per day per individual discriminated against for each day the plan does not comply with the requirement), part 7 of ERISA (a civil action to enjoin a noncompliant act or practice or for appropriate equitable relief), or ~~t~~Title XXVII of the PHS Act (civil money penalties of \$100 per day per individual discriminated against for each day the plan does not comply with the requirement). Thus, if a self-insured plan fails to comply with Code section 105(h), highly compensated individuals lose a tax benefit; if an insured group health plan fails to comply with Code section

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105(h), the plan is subject to a civil action to compel it to provide nondiscriminatory benefits and the plan or plan sponsor is subject to an excise tax or civil money penalty of \$100 per day per individual discriminated against. Rather than restate the rules under section 105(h) of the Code, these interim final regulations incorporate by reference those rules and applicable regulations.

Application to grandfathered health plans. The rules prohibiting discrimination in favor of highly compensated individuals by insured group health plans do not apply to grandfathered health plans (but the rules of Code section 105(h) continue to apply to self-insured plans).

D. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815-2719A T, 29 CFR 2590.715-2719A, 45 CFR 147.XXX)

Section 2719A of the PHS Act imposes, with respect to a group health plan, or group or individual health insurance coverage, ~~with a network of providers, both~~ a set of three requirements relating to the choice of a health care professional ~~in a plan with a network of providers~~ and ~~other~~ requirements relating to benefits for ~~the benefits for the receipt of~~ emergency ~~care services~~. The ~~three~~ requirements relating to the choice of health care professional apply only with respect to a plan or health insurance coverage with a network of providers. Thus, a plan or ~~health insurance coverage issuer~~ that has not negotiated with any provider for the delivery of ~~certain services or items of~~ health care but merely reimburses individuals covered under the plan for their receipt of ~~covered services or items~~ health care is not subject to the requirements relating to the choice of a health care professional. However, such plans or health insurance coverage are subject ~~in part to the~~ requirements relating to benefits for ~~benefits for the receipt of~~ emergency ~~care services~~. These interim final regulations ~~reorganize-reorder~~ the statutory requirements so that all three of the requirements relating to the choice of a health care professional are together and add a notice requirement for those three requirements.

1. Choice of Health Care Professional

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~~Section 2719A(a) of the PHS Act~~ The statute and these interim final regulations provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In accordance with paragraph (a)(4) section 2590.715(e) of these interim final regulations, the plan or issuer must provide a notice informing each participant (or in the individual market, the primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

The statute and these interim final regulations impose a requirement for the designation of a pediatrician similar to the requirement for the designation of a primary care physician. Specifically, if a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the notice requirements of paragraph ~~(e)~~ (a)(4) of these interim final regulations. The ~~plan's~~ general terms of the plan or health insurance coverage regarding pediatric care otherwise are unaffected, including any exclusions with respect to coverage of pediatric care.

The statute and these interim final regulations also provide rules for a group health plan, or a health insurance issuer offering group or individual health insurance coverage, that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. In such a case, the plan or issuer may not require authorization or referral

by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology. The plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. Nothing in these interim final regulations precludes the plan or issuer from requiring an in-network obstetrical or gynecological provider to otherwise adhere to policies and procedures regarding referrals, prior authorization for treatments, and the provision of services pursuant to a treatment plan approved by the plan or issuer. The plan or issuer must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the professional who specializes in obstetrics or gynecology as the authorization of the primary care provider. For this purpose, a health care professional who specializes in obstetrics or gynecology is any individual who is licensed under applicable State law to provide obstetrical or gynecological care and is not limited to a physician.

The general terms of the plan or coverage regarding exclusions of coverage with respect to obstetrical or gynecological care are otherwise unaffected. These interim final regulations do not preclude the plan or issuer from requiring that the obstetrical or gynecological provider notify the primary care provider or the plan or issuer of treatment decisions.

When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to: (1) choose a primary care provider or a pediatrician ~~under paragraphs (a) and (b) of this section~~ when ~~group health plans~~ or issuers requires participants or subscribers to designate a primary care physician ~~(either for the participant/subscriber or a child);~~

or (2) obtain obstetrical or gynecological care ~~under paragraph (c)~~ without prior authorization ~~from the plan, issuer or primary care provider~~. Accordingly, ~~paragraph (d) of this section~~ these interim final regulations requires such ~~group health~~ plans and issuers to provide a notice ~~of that right~~ to participants (in the individual market, primary subscribers) of these rights when applicable. Model language ~~for the notices~~ is provided in ~~paragraph (d)~~ these interim final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

~~The notices can be included in existing plan documents and must be provided within 90 days of enrollment. Because the 90 day requirement is the same as the time requirements for ERISA SPDs, group health plans would comply with the timing requirement of paragraph (d) by including the notices into their SPDs. Issuers usually send out policies within 30 of the individual subscriber's enrollment into the coverage, so including the notices into the policy would also satisfy the timing requirement.~~

2. Emergency Services

~~Section 2719A of the PHS Act imposes, with respect to a group health plan or group or individual health insurance coverage with a network of providers, both a set of three requirements relating to the choice of a health care professional in a plan with a network of providers and other requirements relating to the benefits for the receipt of emergency care. These requirements relating to the choice of health care professional apply only with respect to a plan or health insurance coverage with a network of providers. Thus, a plan or health insurance coverage that has not negotiated with any provider for the delivery of certain services or items of~~

~~health care but merely reimburses individuals covered under the plan for their receipt of covered services or items is not subject to the requirements relating to the choice of a health care professional. However, such plans are subject in part to the requirements relating to benefits for the receipt of emergency care. These interim final regulations reorganize the statutory requirements so that all three of the requirements relating to the choice of a health care professional are together and add a notice requirement for those three requirements.~~

Preamble Language for Emergency Services

If a plan or health insurance coverage provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services in a way that is consistent with these interim final regulations. These interim final regulations require that a plan providing emergency services must do so without any prior authorization (even if the services are provided on an out-of-network basis) and without regard to whether the health care provider furnishing the services is a participating network provider with respect to the services. The emergency services must be provided without regard to any other term or condition of the plan or health insurance coverage other than the exclusion or coordination of benefits, an affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code, or applicable cost-sharing requirements. For a plan or health insurance coverage with a network of providers that provides benefits for emergency services~~I, f the emergency services are being provided out of network, the plan or issuer they must be provided without~~ may not impose ~~ing~~ any administrative requirement or limitation on benefits for out-of-network emergency services coverage~~coverage~~ that is more restrictive than the requirements or

limitations that apply to in-network emergency services ~~received from in-network providers,~~
~~and must comply with specific rules for cost-sharing requirements.~~

~~These Additionally, for a plan or health insurance coverage with a network, these~~ interim
final regulations provide rules for cost-sharing requirements for emergency services that are
expressed as a copayment amount or coinsurance rate, and other cost-sharing requirements. Cost-
sharing requirements expressed as a copayment amount or coinsurance rate imposed for out-of-
network emergency services cannot exceed the cost-sharing requirements that would be imposed
if the services were provided in-network. A plan or issuer satisfies this requirement if it provides
benefits for out-of-network emergency services in an amount equal to the greatest of three
possible amounts—

(~~A~~1) The amount negotiated with in-network providers for the emergency service
furnished;

(~~B~~2) The amount for the emergency service calculated using the same method the plan
uses to determine payments for out-of-network services (such as the usual, customary, and
reasonable charges); or

(~~C~~3) The amount paid under Medicare for the emergency service.¹⁵

~~Each of these three amounts is The amount of benefits negotiated with in-network providers for~~
~~the emergency service furnished is~~ calculated excluding any in-network copayment or
coinsurance imposed with respect to the participant, beneficiary, or enrollee.

In connection with determining the first amount above, for plans and health insurance
coverage under which there is no per-service amount negotiated with in-network providers (such
as under a capitation or other similar arrangement), the amount is zero, meaning that the greatest

¹⁵ As of the date of publication of these interim final regulations, these rates are available to the public at
<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf>.

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amount is going to be either the out-of-network amount or the Medicare amount. If

Additionally, with respect to determining the first amount, if a plan or issuer has more than one negotiated amount with in-network providers for a particular emergency service, this analysis
considerse amount is the median of these amounts, excluding any in-network copayment or
coinsurance imposed with respect to the participant, beneficiary, or enrollee. The median is
determined based solely on the number of rates negotiated, irrespective of with how many
providers each rate is negotiated. Thus, for example, if for a given emergency service a plan
negotiated a rate of \$100 with 100 providers, a rate of \$125 with one provider, and a rate of \$150
with one provider, the median would be \$125. (Cost sharing imposed with respect to the
participant, beneficiary or enrollee would be deducted from this amount before determining the
greatest of the three amounts.) Following the commonly accepted definition of median, if there
are an even number of amounts, the median is the average of the middle two. For plans and
health insurance coverage under which there is no per-service amount negotiated with in-
network providers (such as under a capitation or other similar arrangement), this amount is equal
to zero.

Although a plan or health insurance coverage is generally not constrained by the
requirements of PHS Act section 2719A for cost-sharing requirements other than copayments or
coinsurance, these interim final regulations include an anti-abuse rule with respect to such other
cost-sharing requirements so that the purpose of limiting copayments and coinsurance for
emergency services to the in-network rate cannot be thwarted by manipulation of these other
cost-sharing requirements. The amount paid under Medicare is the amount of benefits paid
under part A or part B of title XVIII of the Social Security Act for the emergency service,

~~excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. These rates are available to the public at: [insert website].~~

Accordingly, any other cost-sharing requirement, such as a deductible or out-of-pocket maximum, may be imposed with respect to out-of-network emergency services if the cost-sharing requirement generally applies to out-of-network benefits. Specifically, a deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. Similarly, if an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services. ~~A plan or health insurance coverage could fashion these other cost-sharing requirements so that a participant, beneficiary, or enrollee is required to pay less for emergency services than for general out-of-network services; the anti-abuse rule merely prohibits a plan or health insurance coverage from fashioning such rules so that a participant, beneficiary, or enrollee is required to pay more for emergency services than for general out-of-network services. Plans and health insurance coverage can always be more generous to participants, beneficiaries, and enrollees, by waiving the application of cost-sharing requirements like deductibles and out-of-pocket maximums to out-of-network emergency services.~~

~~In applying the rules relating to emergency services, the statute and these interim final regulations define the terms emergency medical condition, emergency services, and stabilize. These terms are defined generally in accordance with their meaning under Emergency Medical Treatment and Active Labor Act (EMTALA), section 1867 of the Social Security Act. There are, however, some variances from the EMTALA definitions. For example, emergency medical condition is defined in terms of what a prudent layperson might expect to happen if immediate medical attention is not sought.~~

For purposes of these interim final regulations, the term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) and incorporates a “prudent layperson” standard. This standard considers what a prudent layperson (someone with an average knowledge of health and medicine) could reasonably expect to result in placing the health of an individual in serious jeopardy, serious impairment to bodily functions, or dysfunction of any bodily organ or part.

The term emergency services is defined in accordance with section 1867 of the Social Security Act, to mean medical screening examinations within the capability of the emergency department of a hospital (including ancillary services routinely available to the emergency department to evaluate an emergency medical condition) and further medical examination and treatment to stabilize the patient (to the extent such services are within the capabilities of the staff and facilities available at the hospital).

The term to stabilize also incorporates by reference a definition from section 1867(e)(3) of the Social Security Act, to mean, with respect to an emergency medical condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

~~{emergency care description to follow rest of preamble for this section}~~

Under these interim final regulations, a plan or health insurance coverage that provides any benefits with respect to services in an emergency department of a hospital must provide benefits for emergency service without the need for any prior authorization determination, even if the services are provided on an out-of-network basis. This requirement to any plan or health insurance coverage providing benefits for emergency services, even if the plan or health

~~insurance coverage does not have a network of providers. For a plan or health insurance coverage with any network of providers and that provides any benefits for emergency services, the benefits for emergency services must be provided without regard to whether the health care provider furnishing the services is a participating network provider with respect to the services and, if the services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers. Additional rules apply to network plans and health insurance coverage with respect to cost-sharing requirements expressed as a copayment amount or a coinsurance rate for out-of-network emergency care (discussed in the following paragraphs). Finally, for both network and non-network plans, the benefits for emergency services must be provided without regard to any other term or condition other than (1) the exclusion or coordination of benefits; (2) an affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code; and (3) applicable cost sharing (other than the specific rules for copayments and coinsurance of network plans).~~

~~For network plans, any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to the participant, beneficiary, or enrollee if the services were provided in-network. Although this rule is clear as to the maximum copayment or coinsurance that a participant, beneficiary, or enrollee is responsible for, in the situation where an out-of-network provider charges a higher rate for an emergency service than a negotiated rate with in-network providers, the provisions of PHS Act section 2719A do not make clear what should happen with respect to the excess of the~~

~~amount charged by the out-of-network provider over the in-network rate. While section 2719A does not provide a clear answer to this issue, section 1302(c) of the Affordable Care Act defines cost-sharing to exclude balance billing. [refine this previous description based on actual statutory language.] In accordance with that provision, these interim final regulations establish rules for determining the amount that a plan or health insurance coverage must pay with respect to emergency services provided out-of-network to satisfy the requirement under PHS Act section 2719A that only an amount or rate not exceeding the in-network copayment or coinsurance may be imposed with respect to a participant, beneficiary, or enrollee.~~

~~A plan or health insurance issuer satisfies this requirement with respect to an emergency service if it provides benefits in an amount equal to the greatest of three amounts:-~~

~~(1) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.~~

~~(2) The amount for the emergency service calculated using the same method the plan uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges), excluding any in-network copayment or coinsurance imposed on the participant, beneficiary, or enrollee.~~

~~(3) The amount paid under Medicare for the emergency service, excluding any in-network copayment or coinsurance imposed on the participant, beneficiary, or enrollee. [link to CMS cite for determining the Medicare rate?]~~

~~In a case in which there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the first amount is zero, meaning that the highest rate is going to be either the out-of-network amount or the Medicare amount. Also~~

with respect to the first of these three amounts, if there is more than one amount negotiated with in-network providers for the emergency service, the amount is the median. The median is determined based solely on the number of rates negotiated, irrespective of with how many providers each rate is negotiated. Thus, for example, if for a given emergency service a plan negotiated a rate of \$100 with 100 providers, a rate of \$125 with one provider, and a rate of \$150 with one provider, the median would be \$125. (Cost sharing imposed with respect to the participant, beneficiary or enrollee would be deducted from this amount before determining the highest of the three amounts.) Following the standard definition of median, if there are an even number of amounts, the median is the average of the middle two.

Although a plan or health insurance coverage is generally not constrained by the requirements of PHS Act section 2719A for cost sharing requirements other than copayments or coinsurance, these interim final regulations include an anti-abuse rule with respect to such other cost sharing requirements so that the purpose of limiting copayments and coinsurance for emergency services to the in-network rate cannot be thwarted by manipulation of these other cost sharing requirements. Accordingly, any cost sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services. A plan or health insurance coverage could fashion these other cost sharing requirements so that a participant, beneficiary, or enrollee is required to pay less for emergency services than for general out-of-network services;

~~the anti-abuse rule merely prohibits a plan or health insurance coverage from fashioning such rules so that a participant, beneficiary, or enrollee is required to pay more for emergency services than for general out-of-network services.~~

~~In applying the rules relating to emergency services, the statute and these interim final regulations define the terms emergency medical condition, emergency services, and stabilize. These terms are defined generally in accordance with their meaning under EMPALA [what's the full name?], section 1867 of the Social Security Act. There are some variances from the EMPALA definitions though. For example, emergency medical condition is defined in terms of what a prudent layperson might expect to happen if immediate medical attention is not sought.~~

Application to grandfathered health plans. The statute and these interim final regulations relating to certain patient protections do not apply to grandfathered health plans. However, other Federal or State laws related to these patient protections may apply regardless of grandfather status.

E. Individual Market and Non-Federal Governmental Plan Reforms

1. References to the Public Health Service Act

Conforming changes are made throughout Parts 144 and 146 to reflect changes made by the Patient Protection and Affordable Care Act (Affordable Care Act), which renumbered certain sections of title XXVII of the Public Health Service Act (PHS Act).

2. Definitions (45 CFR 144.103)

The definition of “policy year” is added and it is defined as the 12-month period that is designated in the policy documents of individual health insurance coverage. If the policy document does not designate a policy year (or no such document exists), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year. The Affordable Care Act uses the term “plan year” in referring to the period of coverage in both the individual and group health insurance markets. The term “plan year,” however, is generally recognized as having only relevance in the group health insurance market. Accordingly, these interim final regulations substitute the term “policy year” for “plan year” in defining the period of coverage in the individual health insurance market.

These interim final regulations revise the definition of “preexisting condition exclusion” to clarify that the denial of an application for coverage because of a preexisting condition in the individual health insurance market is a preexisting condition exclusion. This definition at 45 CFR 144.103 is cross-referenced in both 45 CFR 146.111(a)(1) and 45 CFR 147.2704, and it applies in both the group and individual health insurance markets, and also to entities that provide coverage to Federally eligible individuals pursuant to 45 CFR Part 148.

3. Treatment of Non-Federal Governmental Plans (45 CFR 146.180)

As noted, the Affordable Care Act made numerous changes to ~~the~~ Title XXVII of the PHS Act, including to former section 2721(b)(2), which permitted the sponsor of a self-funded non-Federal governmental plan, as defined in 45 CFR 144.103, to elect to exempt the plan from certain requirements of ~~the~~ Title XXVII of the PHS Act.¹⁶ Section 1001(4) of the Affordable Care Act re-designated section 2721 as section 2735. Affordable Care Act section 1562(a)(2)

¹⁶ This is referred to here as ~~the an~~ “opt-out ~~provision~~election.”

amended section 2735 by adding a new subparagraph (a)(2)(E), which prohibits a sponsor of a self-funded non-Federal governmental plan from electing to exempt the plan from ~~s~~Subparts I and II in ~~P~~part A of the revised ~~t~~itle XXVII. Affordable Care Act section 1562(c)(12) then amended section 2735, including re-designating subsection (b)(2) as subsection (a)(2), and then by redesignating section 2735 as section 2722.

Subpart I (“General Reform”) contains the substance of the provisions of the original ~~s~~Subpart 1 of ~~p~~Part A of title XXVII of the PHS Act, including limitations on preexisting condition exclusion periods, requirements for special enrollment, and prohibitions against discriminating against individual participants and beneficiaries based on health status or genetic information. Therefore, as a result of section 2722(a)(2)(E), the sponsor of a self-funded non-Federal governmental plans cannot opt out of (elect to be exempted from) the foregoing provisions, which are now in ~~S~~subpart I, starting with plan years beginning on or after September 23, 2010.

However, while section 2722(a)(2)(E) precludes an opt-out election with respect to the new subparts I and II of ~~p~~Part A, an opt-out election is still permitted with respect to the provisions in ~~s~~Subpart 2 of ~~p~~Part A. Affordable Care Act section 1001(2) re-designated sections 2704 through 2707 (which formerly set forth the provisions relating to the Newborns’ and Mothers’ Health Protection Act of 1996, the Mental Health Parity Act of 1996 (as amended by the Mental Health Parity and Addiction Equity Act of 2008), the Women’s Health and Cancer Rights Act of 1998, and Michelle’s Law (2008)) as new sections 2725 through 2728, respectively, which are contained in a revised ~~s~~Subpart 2, “Exclusion of Plans; Enforcement; Preemption.”¹⁷ A sponsor of a self-funded non-Federal governmental plan may continue to elect

¹⁷ The Affordable Care Act created Subparts I and II of Part A, but did not remove Subpart 2. Therefore, Subpart II (Roman numeral) and Subpart 2 (Arabic numeral) are separate, coexisting subparts.

to exempt its plan from the requirements of new sSubpart 2 (which is separate from sSubpart II) of pPart A of title XXVII since the prohibition in section 2722(a)(2)(E) does not reference sSubpart 2.

Affordable Care Act section 1004(a) provides that the amendments made by section 1001 are “effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act[.]” The Affordable Care Act was enacted on March 23, 2010. Therefore, the amendments made by section 1001, as further amended by subsections (a) and (c)(12) of section 1562, are effective for plan years beginning on or after September 23, 2010.

The Affordable Care Act includes-makes no exception for plan years that are governed by a previously ratified collective bargaining agreement under which the plan sponsor has elected to exempt athe self-funded non-Federal governmental plan from one or more requirements of sSubpart 1 (as it was designated prior to enactment of the Affordable Care Act). Section 1251 of the Affordable Care Act has special rules for "grandfathered" plans, including an exception in subsection (d) for collectively bargained plans. However, the exception only applies for "**health insurance coverage** maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this Act." (Emphasis added.) New section 2722(a)(2)(B)(ii) (former section 2721(b)(2)(B)(ii)) of the PHS Act, however, indicates-provides that an opt-out election made by the sponsor of a group health plan maintained pursuant to a collective bargaining agreement remains in effect “for the term of such agreement.” Since this provision was not amended by the Affordable Care Act, HHS’s we-view is that it takes precedence over the provisions of section 1251(d) of the Affordable Care Act. Accordingly, these interim final regulations state that a group health plan that is maintained pursuant to a collective bargaining agreement that was

ratified before March 23, 2010 and that has been exempted from any provision in the former Subpart 1 will not have to come into compliance with those provisions until beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement.

The sponsor of a self-funded ~~Non~~non-federal governmental plans not maintained pursuant to a collective bargaining agreement will not be permitted to elect to opt-out of the provisions in the former ~~s~~Subpart 1 for plan years beginning on or after September 23, 2010. Although section 1251(b) of the Affordable Care Act provides grandfathering protection for plans that existed before March 23, 2010, opt-out elections initially submitted or renewed on or after the amendment effective date of ~~March~~September 23, 2010 for any provision in the former ~~s~~Subpart 1 are not subject to that protection.

In addition to revisions that reflect the changes made by the Affordable Care Act discussed above, section 146.180 is further revised to make certain changes that are unrelated to the Affordable Care Act, such as adding the requirements of Michelle's ~~L~~Aaw to the list of title XXVII requirements set forth at section 146.180(a)(1) from which self-funded non-Federal governmental plans may be exempted, updating the address to which an opt-out election should be submitted, updating an example to reflect more recent dates, and removing outdated text.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of

the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, numerous provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. ~~Grandfathered~~

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~~health plans are exempt from many of these provisions while group health plans and group and individual health insurance coverage that are not grandfathered health plans must comply with them. The determination of whether a plan or health insurance coverage is a grandfathered health plan therefore could substantially affect the design of the plan or health insurance coverage.~~

~~The six month period between the enactment of the Affordable Care Act and the applicability of many of the provisions affected by grandfather status would not allow sufficient time for the Departments to draft and publish proposed regulations, receive and consider comments, and draft and publish final regulations. Moreover, regulations are needed well in advance of the effective date of the requirements of the Affordable Care Act.~~

~~Many group health plans and health insurance coverage that are not grandfathered health plans must make significant changes in their provisions to comply with the requirements of the Affordable Care Act. Moreover, plans and issuers considering other modifications to their terms need to know whether those modifications will affect their status as grandfathered health plans.~~ Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Yet, the requirements in these regulations require significant lead time in order to implement.

For example, in the case of the requirement under PHS Act section 2711 prohibiting overall lifetime dollar limits, these interim final regulations require that an enrollment period be provided for an individual whose coverage ended by reason of reaching a lifetime limit no later than the first day this requirement takes effect. Preparations presumably would have to be made to put such an enrollment process in place. In the case of requirements for emergency care under PHS Act section 2719A, plans and issuers need to know how to process charges by out-of-network providers by as early as the first plan or policy year beginning on or after September 23, 2010. With respect to all the changes that would be required to be made under these interim final regulations, whether adding coverage of children with a preexisting condition under PHS Act section 2704, or determining the scope of rescissions prohibited under PHS Act section 2712, group health plans and health insurance issuers have to be able to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or

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policy benefits, and these premiums and plan or policy changes would have to receive necessary approvals in advance of the plan or policy year in question.

Accordingly, in order to allow plans and health insurance coverage to be designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact and Paperwork Burden

Approximately four percent of large employer plans, eight percent of small employer PPO plans, and 19 percent of individual market plans currently have annual limits. Although available data show that very few health insurance plans impose annual limits, at least half of small group plans and over 75 percent of policies in the individual market impose lifetime limits.

The 2009 Kaiser Family Foundation/HRET Survey of Employers found that less than one percent of covered workers had lifetime limits less than \$1 million, 16 percent had limits between \$1 million and \$1.99 million, 43 percent had lifetime limits of \$2 million or more, and 41 percent had no lifetime maximum.¹⁸ Of those enrollees in indemnity plans with lifetime limits, 63 percent of single enrollees and 44 percent of family enrollees had lifetime maximums less than \$2 million while less than one percent of enrollees in network-based arrangements, such as HMOs, PPOs, or high deductible health plans with savings options had lifetime maximums less than \$2 million. While it is possible that those plans with lifetime limits will switch to annual limits prior to the elimination of annual limits in 2014, group health plans and health insurance issuers could use a number of changes to benefit design to mitigate any potential premium increases. [-----

[This phased-in approach provides ample opportunity for plans with relatively low annual limits (e.g., \$100,000, \$250,000, or \$500,000) to more gradually make adjustments that might smooth any increase in costs that might result from the increased minimum annual limits under these interim final regulations. The proposed annual limit levels ensure that the vast majority of individuals who may experience high medical costs during the year will continue to have access to coverage.]

Comment [b2]: Can we get rid of this whole paragraph? Cross reference the discussion in the economic analysis that goes over these same statistics?

If not, use cite for the 1st sentence from economic analysis cite to Mercer survey (FN 31 in old draft)

Comment [b3]: This was moved from our part of the preamble (II) per the comment above.

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a,

¹⁸ See the Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), at <http://ehbs.kff.org/pdf/2009/7936.pdf>.

1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

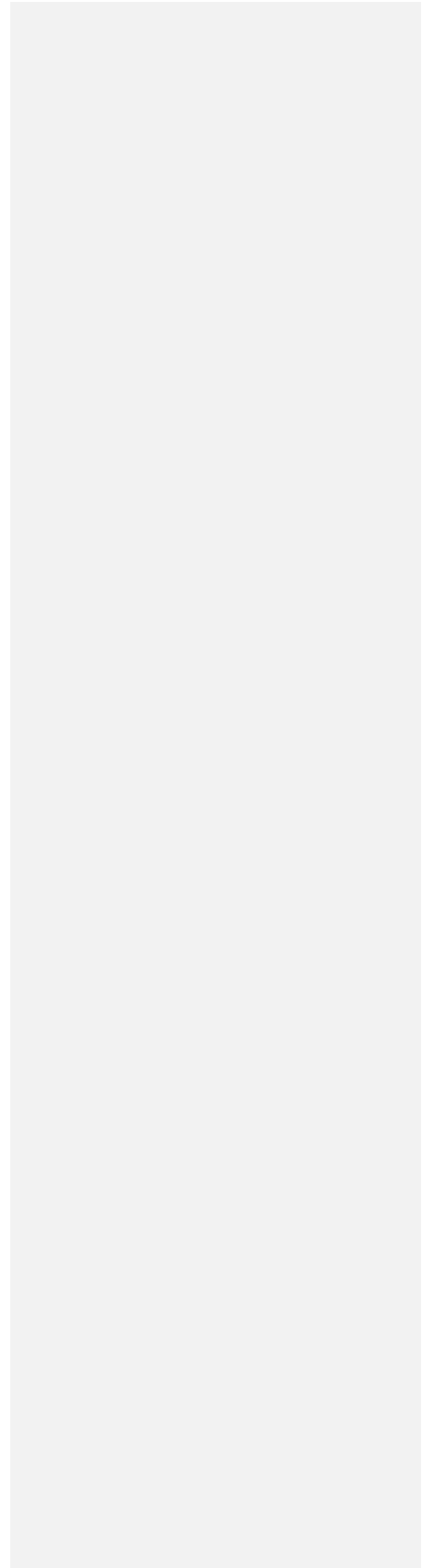
Steven T. Miller
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved:

Michael F. Mundaca
Assistant Secretary of the Treasury (Tax Policy).

Signed this _____ day of _____, 2010.

Phyllis C. Borzi
Assistant Secretary
Employee Benefits Security Administration
Department of Labor



Approved: _____

Jay Angoff,

Director,

Office of Consumer Information and Insurance
Oversight.

Approved: _____

Kathleen Sebelius,

Secretary, Department of Health and Human
Services.

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR HEALTH INSURANCE

PORTABILITY AND RENEWABILITY FOR GROUP HEALTH PLANS

1. The authority citation for Part 2590 continues to read as follows:

Authority:

29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

Subpart B—Other Requirements

2. Section 2590.701-2 is amended by revising the definition of preexisting condition exclusion to read as follows:

§ 2590.701-2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion

includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR Part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

3. Section 2590.701-3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) Preexisting condition exclusion—(1) Defined—(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning of § 2590.701-2 of this Part.

* * * * *

4. Section 2590.715-2714 is amended by revising paragraph (d) to read as follows:

(d) Uniformity irrespective of age.—(1) In general. Subject to paragraph (d)(2) of this section, the terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(2) Preexisting condition exclusions for children age 19 and older before 2014. For plan years (in the individual market, policy years) beginning before January 1, 2014, the terms of the plan or health insurance coverage may impose a preexisting condition exclusion (consistent with the rules of section 2590.701-3 of this Part) on children who are age 19 or older even though this is prohibited with respect to children under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

5. Section 2590.715-2704 is added to Subpart C to read as follows:

§ 2590.715-2704 Prohibition of preexisting condition exclusions.

(a) In general. (1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701-2 of this Part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this Part):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) Conclusion. In this Example 1, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) Facts. Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition. (The denial of an application for coverage based on a preexisting condition exclusion also violates PHS Act section 2702 (guaranteed availability of coverage) and PHS Act section 2705 (prohibition against discrimination based on health status) for policy years beginning on or after January 1, 2014.)

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the requirements of this section apply for plan years beginning on or after January 1, 2014; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) Early applicability date for children. The requirements of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

(4) Examples. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16 year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child went more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) Conclusion. In this Example 1, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) Facts. Individual G applies for a policy of family coverage in the individual market for G, G's spouse, and G's 13 year-old child. The issuer denies the application for coverage on March 1, 2011 because G's 13 year-old child has autism.

(ii) Conclusion. In this Example 2, the issuer's denial of G's application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the March 1, 2011 denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to G's 13 year-old child.

6. Section 2590.715-2711 is added to Subpart C to read as follows:

§2590.715-2711 No lifetime or annual limits.

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(a) Prohibition—(1) Lifetime limits. Except as provided in paragraph (b), a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) Annual limits—(i) General rule. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) Condition-based exclusions. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Thus, a dollar limit on benefits for a condition cannot be applied to restrict essential health benefits. Other requirements of Federal or State law may require coverage of certain benefits.

(c) Definition of essential health benefits. The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) Restricted annual limits permissible prior to 2014—(1) In general. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year or policy year beginning on or after September 23, 2010 but before September 23, 2011, \$750,000.

(ii) For a plan year or policy year beginning on or after September 23, 2011 but before September 23, 2012, \$1,250,000.

(iii) For plan years or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2,000,000.

(2) Only essential health benefits taken into account. In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(e) Transitional rules for individuals whose coverage ended by reason of reaching a lifetime limit.

(1) In general. The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage ended under a group health plan or group health insurance coverage by reason of reaching a lifetime limit on the dollar value of all benefits for any individual the availability of dependent coverage of children ended before the attainment of age 26 (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for coverage under a group health plan or group health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) Opportunity to enroll required. (i) If a group health plan, or group health insurance coverage, in which an individual described in paragraph (e)(1) of this section is eligible to enroll (or is required to become eligible to enroll) is the plan or coverage in which the individual's coverage ended (or did not begin) for the reasons described in paragraph (e)(1)(i) of this section, and if the plan, or the issuer of such coverage, is subject to the requirements of this section, the plan and the issuer are required to give the child an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This opportunity (including the written notice) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The written notice must include a statement that any individual whose coverage ended by reason of reaching a lifetime limit on the dollar value of all benefits is eligible to enroll in the plan or coverage. The notice may be provided to an employee on behalf of the employee's dependent. In addition, the notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. If a notice satisfying the requirements of this paragraph (e)(2) is provided to an employee whose dependent is entitled to an enrollment opportunity under this paragraph (e), the obligation to provide the notice of enrollment opportunity under this paragraph (e)(2) with respect to that dependent is satisfied for both the plan and the issuer.

(3) Effective date of coverage. In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §2590.701-6(d) of this Part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) Examples. The rules of this paragraph (e) are illustrated by the following examples:

Comment [blb1]: Need to revise – these are from 2714.

Example 1. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan allows children of employees to be covered under the plan until age 19, or until age 23 for children who are full-time students. Individual B, an employee of Y, and Individual C, B's child and a full-time student, were enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, C turns 23 years old and loses dependent coverage under Y's plan. On or before January 1, 2011, Y's group health plan gives B written notice that individuals who lost coverage by reason of ceasing to be a dependent before attainment of age 26 are eligible to enroll in the plan, and that individuals may request enrollment for such children through February 14, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) Conclusion. In this Example 1, the plan has complied with the requirements of this paragraph (f) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan allows children of employees to be covered under the plan until age 22. Individual D, an employee of Z, and Individual E, D's child, are enrolled in family coverage under Z's group

health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E turns 22 years old and ceases to be eligible as a dependent under Z's plan and loses coverage. D drops coverage but remains an employee of Z.

(ii) Conclusion. In this Example 2, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) Facts. Same facts as Example 2, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) Conclusion. In this Example 3, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 4. (i) Facts. Same facts as Example 2, except that E elected COBRA continuation coverage.

(ii) Conclusion. In this Example 4, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll other than as a COBRA qualified beneficiary (and must provide, by that date, written notice of the opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 5. (i) Facts. Employer X maintains a group health plan with a calendar year plan year. Prior to 2011, the plan allows children of employees to be covered under the plan until the child attains age 22. During the 2009 plan year, an individual with a 22-year old child joins the plan; the child is denied coverage because the child is 22.

(ii) Conclusion. In this Example 5, notwithstanding that the child was not previously covered under the plan, the plan must provide the child, not later than January 1, 2011, an opportunity to enroll (including written notice to the employee of an opportunity to enroll the child) that continues for at least 30 days, with enrollment effective not later than January 1, 2011.

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

7. Section 2590.715-2712 is added to Subpart C to read as follows:

§ 2590.715-2712 Rules regarding rescissions.

(a) Prohibition on rescissions—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group.

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. In addition, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission.

(3) The rules of this paragraph (a) are illustrated by the following example:

Example. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this Part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A was treated for acne six years ago. A is later diagnosed with breast cancer and seeks benefits

under the plan. On or around the same time, the issuer receives information about A's prior treatment for acne, which was not disclosed in the questionnaire.

(ii) Conclusion. In this Example, the plan cannot rescind A's coverage because A's failure to disclose the prior treatment for acne was not fraudulent or an intentional misrepresentation of material fact.

(b) Compliance with other requirements. Other requirements of Federal or State law may apply in connection with a rescission of coverage, including the requirement under PHS Act section 2719(a)(1)(C), which requires a plan or an issuer to allow an enrollee to continue coverage pending the outcome of an appeal of a coverage or claim determination.

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

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78. Section 2590.715-2716 is added to Subpart C to read as follows:

§ 2590.715-2716 Prohibiting discrimination in favor of highly compensated individuals.

(a) In general. A group health plan (other than a self-insured plan) must satisfy the requirements of section 105(h)(2) of the Internal Revenue Code that apply to self-insured medical reimbursement plans (prohibiting discrimination in favor of highly compensated individuals as to eligibility to participate and as to the benefits provided).

(b) Rules and definitions. The provisions of section 105(h) of the Internal Revenue Code (and applicable regulations) described in this paragraph (b) apply for purposes of this section.

(1) Nondiscrimination rules. The nondiscriminatory eligibility classification rules of section 105(h)(3) of the Internal Revenue Code and the nondiscriminatory benefits rule of section 105(h)(4) of the Internal Revenue Code apply to a group health plan (other than a self-

insured plan) under this section as if the group health plan were a self-insured medical reimbursement plan.

(2) Controlled group rules. The controlled group rules and other related rules referenced in section 105(h)(8) of the Internal Revenue Code apply for purposes of this section.

(3) Highly compensated individual defined. Highly compensated individual has the meaning given in section 105(h)(5) of the Internal Revenue Code.

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.

89. Section 2590.715-2719A is added to Subpart C to read as follows:

§ 2590.715-2719A Patient protections.

(a) Choice of health care professional – (1) Designation of primary care provider—(i) In general. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (e) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(2)(i) Example. The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) Facts. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any

Comment [b2]: Preamble: if a plan has no network of providers, 2719A does not apply.

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participating primary care provider who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (e) of this section regarding the ability to designate a primary care provider.

(ii) Conclusion. In this Example, the plan has satisfied the requirements of paragraph (a) of this section.

(2) Designation of pediatrician as primary care provider—(i) In general. If a group health plan or health insurance issuer offering group or individual health insurance coverage requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the rules of paragraph (e) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) Construction. Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) Examples. The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An HMO designates for each enrollee a physician who specializes in internal medicine to serve as the primary care provider for the enrollee and the enrollee's family. Enrollee A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

(ii) Conclusion. In this Example 1, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (c).

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Example 2. (i) Facts. Same facts as Example 1, except that A takes A's child to B for treatment of the child's severe peanut allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this paragraph (c) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access. A group health plan or health insurance issuer offering group or individual health insurance coverage described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider described in paragraph (a)(3)(i)(B) of this section) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual who is licensed under applicable State law to provide obstetrical or gynecological care and is not limited to a physician.

(B) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) Application of paragraph. A group health plan or health insurance issuer offering group or individual health insurance coverage is described in this paragraph if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) Construction. Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) Examples. The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(ii) Conclusion. In this Example 1, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) Facts. Same facts as Example 1 except that A seeks gynecological services from C, an out-of-network provider.

(ii) Conclusion. In this Example 2, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) Facts. Same facts as Example 1 except that the group health plan requires B to inform A's designated primary care physician of treatment decisions.

(ii) Conclusion. In this Example 3, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for a scheduled cesarean section.

(ii) Conclusion. In this Example 4, the plan requirement for prior authorization before providing benefits for a scheduled cesarean section does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to services for treatments, it does not restrict access to any providers specializing in obstetrics or gynecology.

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(4) Notice of right to designate a primary care provider. (i) In general. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights –

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, that any participating physician who specializes in pediatrics as the child's primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) Model language. The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

[insert Jim HW assignment]

(b) Coverage of emergency services.—(1) Scope. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, [offers or] provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) General rules. A plan or issuer subject to the requirements ~~of this part~~ paragraph (b) ~~of this section~~ must provide coverage for emergency services in the following manner –

(i) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the services is a participating network provider with respect to the services;

(iii) If the services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, ~~(other than =~~

~~(A) the~~ The exclusion of or coordination of benefits;

~~(B) or a~~ An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code; ~~and or~~

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(C) ~~other than a~~Applicable cost sharing).

(3) Cost-sharing requirements – (i) Copayments and coinsurance. Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to the participant, beneficiary, or enrollee if the services were provided in-network. A group health plan or health insurance issuer satisfies this requirement with respect to an emergency service if it provides benefits in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section.

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed ~~on~~with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median, excluding any in-network copayment or coinsurance imposed ~~on~~with respect to the participant, beneficiary, or enrollee. If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar arrangement), the amount under this paragraph (b)(3)(i)(A) is zero.

(B) The amount for the emergency service calculated using the same method the plan uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges), excluding any in-network copayment or coinsurance imposed ~~on~~with respect to the participant, beneficiary, or enrollee.

(C) The amount paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

Comment [b3]: Note for preamble: need to describe where these rates are available to the public.

(ii) Other cost sharing. Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

Comment [b4]: Notes for preamble on deductibles and OOP max: states can always be more strict, plans can always be more generous.

(iii) Examples. The rules of this paragraph (b)(23) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to services in an emergency department of a hospital.

Example 1. (i) Facts. A group health plan imposes a 25 percent coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual provides prior notice to the plan within two business days before after the day an individual receives screening or treatment in admission to the an emergency department, the plan reduces the coinsurance rate to 15 percent.

(ii) Conclusion. In this Example 1, the notice requirement to provide notice in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required notice before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a 25 percent coinsurance responsibility on individuals who are furnished emergency services. If a covered individual provides prior notice to the plan before admission to the emergency department of an out of network provider, the plan reduces the coinsurance rate to 15 percent.

(ii) Conclusion. In this Example 2, the notice requirement violates the requirement that the plan cover emergency services with an out of network provider without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in network providers. is the correct, because arguably the out of network gets better treatment than in network

~~with notice. May be unnecessary, plans presumably would just impose on both in and out of network]~~

Example 32. (i) Facts. A group health plan imposes a \$60 copayment on emergency services without preauthorization, ~~whether provided in network or out of network.~~ If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition. ~~The plan also waives the copayment where emergency services are not preauthorized if it later determines that the medical condition was an emergency medical condition.~~

(ii) Conclusion. In this Example 32, ~~by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization,~~ the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. ~~(By contrast, if, to have the copayment waived, the plan merely required that it receive notification rather than grant authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)~~

Example 3. (i) Facts. Same facts as Example 2, except that the plan also waives the copayment where emergency services are not preauthorized if it later determines that the medical condition was an emergency medical condition as defined in this section.

(ii) Conclusion. In this Example 3, ~~the plan does not violate the requirement because the plan does not impose the copayment if the individual has an emergency medical condition.~~ Thus, there is no prior authorization requirement in order to receive coverage for an emergency medical condition.

Example 4. (i) Facts. A group health plan covers ~~an individual~~s who receives emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with ~~200 in-network~~ providers with respect to ~~the type of a certain~~ emergency service~~s~~ furnished to the individual. ~~Under the agreements, Each provider has agreed to provide the service for a certain amount. Among all the providers there are five amounts: 50 providers receive \$85, for the service, 130 providers receive \$100, for the service, 15 providers receive \$110, for the service, three providers receive \$125-120, and for the service and two providers receive \$150 for the service.~~ Under the agreement, the plan agrees to pay the providers 80 percent of the agreed amounts, with the ~~individual~~patient receiving the services responsible for the remaining 20 percent.

(ii) Conclusion. In this Example 4, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section ~~with respect to the emergency services furnished to the individual~~ is 80 percent of \$110 (\$88).

Example 5. (i) Facts. Same facts as Example 4. ~~One month later~~Subsequently, the plan adds a provider to its network and agrees to pay the provider 80 percent of \$170 for the emergency services, with the ~~individual~~patient responsible for the remaining 20 percent.

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Subsequently, an individual covered by the plan receives the emergency services from an out-of-network provider and is charged \$125.

(ii) Conclusion. In this Example 5, the median amount among those agreed to for~~under paragraph (b)(3)(i)(A) of this section with respect to~~ the emergency services ~~furnished is \$115.~~ (Because there is no one middle amount among \$85, \$100, \$110, \$120, \$150, and \$170, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is to the individual is 80 percent of \$115 (\$92). ~~Because there is no one middle amount, the median is the average of the two middle amounts, 80 percent of \$110 and 80 percent of \$120.~~

Example 6. (i) Facts. Same facts as Example 5. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50 percent of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency services received by the individual ~~in Example 5~~, the reasonable amount calculated using this method is ~~\$116~~. The amount that would be paid under Medicare for the emergency services, excluding any copayment or coinsurance for the ~~furnished services~~, would be \$80.

(ii) Conclusion. In this Example 6, the plan is responsible for paying \$92.80, 80 percent of \$116. The median amount ~~of amounts among those agreed to for the emergency service paid network providers is \$115 and the amount the plan would pay is \$92 (80 percent of \$115);~~ the amount calculated using the same method the plan uses to determine payments for out-of-network services ~~is \$116;~~ excluding the in-network 20 percent coinsurance, is \$92.80; ~~and the Medicare payment is \$80;~~ ~~Thus, the greatest amount is \$92.80. The individual patient is responsible for the remaining \$32.20 charged by the out-of-network provider.~~

Example 7. (i) Facts. Same facts as Example 6. The group health plan generally imposes a \$250 deductible for in-network health care. ~~With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible~~ (covered in-network claims are credited against the deductible). The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of networks.

(ii) Conclusion. In this Example 7, the plan is not responsible for paying anything with respect to the emergency services furnished by the out-of-network provider because the covered individual has not satisfied the higher out-of-network deductible ~~(which that applies generally to all health care provided by out-of-network providers);~~

(4) Definitions. The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) ~~such so~~ that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions, and clause (iii) refers to serious dysfunction of any bodily organ or part.)

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(ii) Emergency services. The term emergency services means, with respect to an emergency medical condition –

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

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(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

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(iii) Stabilize. The term to stabilize, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

~~—— (c) Access to pediatric care — (1) Pediatric care. If a group health plan or health insurance issuer offering group or individual health insurance coverage requires or provides for the~~

designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer. In such a case, the plan or issuer must comply with the rules of paragraph (c) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

———(2) Construction. Nothing in paragraph (c)(1) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(3) Examples. The rules of this paragraph (c) are illustrated by the following examples:

Example 1. (i) Facts. An HMO designates for each enrollee a physician who specializes in internal medicine to serve as the primary care provider for the enrollee and the enrollee's family. Enrollee A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

(ii) Conclusion. In this Example 1, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (c).

Example 2. (i) Facts. Same facts as Example 1, except that A takes A's child to B for treatment of the child's severe peanut allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this paragraph (c) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

Example 3. (i) Facts. Same facts as Example 1, except that A wishes to designate as a primary care provider for her child a pediatrician who is an Allopathic Physician (MD). Only pediatricians who are Doctors of Osteopathic Medicine (DO), however, participate in HMO's network.

~~(ii) Conclusion. In this Example 3, the HMO has not violated the requirements of this paragraph (c) because A can still designate a participating pediatrician as the primary care provider for A's child. The fact that there are no pediatricians who are Allopathic Physicians who participate in the HMO's network does not violate this paragraph (c).~~

~~—— (d) Patient access to obstetrical and gynecological care — (1) General rights — (i) Direct access. A group health plan or health insurance issuer offering group or individual health insurance coverage described in paragraph (d)(2) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider described in paragraph (d)(2)(ii) of this section) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. Such a professional must agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.~~

~~—— (ii) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (d)(2) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (d)(1)(i) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.~~

~~—— (2) Application of paragraph. A group health plan or health insurance issuer offering group or individual health insurance coverage is described in this paragraph if the plan or issuer —~~

~~—— (i) Provides coverage for obstetrical or gynecological care; and~~

~~—— (ii) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.~~

~~—— (3) Construction. Nothing in paragraph (d)(1) of this section is to be construed to —~~

~~—— (i) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or~~

~~—— (ii) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.~~

~~—— (4) Examples. The rules of this paragraph (d) are illustrated by the following examples:~~

~~Example 1. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A is a female participant. Participant A requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from Participant A's designated primary care provider for obstetric and gynecological services.~~

~~(ii) Conclusion. In this Example 1, the group health plan has violated the requirements of this section (d) because the plan requires prior authorization from Participant A's primary care provider prior to obtaining gynecological services.~~

~~Example 2. (i) Facts. Same facts as Example 1 except that Participant A seeks gynecological services from Physician C, an out-of-network provider.~~

~~(ii) Conclusion. In this Example 2, the group health plan has not violated the requirements of this section (d) by requiring prior authorization since Physician C is not a participating health care provider.~~

~~Example 3. (i) Facts. Same facts as Example 1 except that Participant A seeks infertility treatments from Physician B. The group health plan does not require prior authorization for the consultation with Physician B but requires prior authorization for infertility treatments.~~

~~(ii) Conclusion. In this Example 3, the group health plan has not violated the requirements of this section (d) since Participant A can get direct access to Physician B for gynecological services and the prior authorization requirement applies only to services for treatments.~~

~~Example 4. (i) Facts. Same facts as Example 1 except that the group health plan requires Physician B to inform Participant A's designated primary care physician of treatment decisions.~~

~~(ii) Conclusion. In this Example 4, the group health plan has not violated the requirements of this section (d) since Participant A has direct access to Physician B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this section.~~

~~—— (e) Notice of requirement to designate a primary care provider. (1) In general. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider under paragraph (a)(1) or (c)(1) of this section, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated.~~

~~—— (2) Model language. The following model language can be used to satisfy the notice requirement described in paragraph (c)(1) of this section:~~

~~{insert Jim HW assignment}~~

~~(f) Applicability date. The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans.~~

~~9. 2722: HHS Opt-out Reg:~~

~~910. Section 146.180 is amended as follows:~~

- ~~A. Revising paragraph (a)(1).~~
- ~~B. Adding a new paragraph (a)(2).~~
- ~~C. Renumbering paragraphs (a)(2), (a)(3) and (a)(4) as (a)(3), (a)(4) and (a)(5), respectively.~~

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- D. Replacing “2706” with “2727” each place it appears in paragraph (a)(1)(i)(F) and in Example 1 of paragraph (a)(3) (previously designated as (a)(2)).
- E. Making a conforming change to paragraph (a)(4)(i) (previously designated as (a)(3)(i)).
- F. Updating paragraph (c) to reflect the current address to which exemption elections may be mailed and providing a facsimile number to which elections may be faxed as an alternative to mailing elections.
- G. Removing the outdated parenthetical reference to § 146.125(a)(2) in paragraph (f)(2)(ii).
- H. Making a conforming change to paragraph (f)(3)(i).
- I. Adding a conforming sentence at the end of Example 1 in paragraph (h)(4)(i).
- J. Updating Example 4 in paragraph (i)(2)(iv).

The revisions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) Requirements subject to exemption—(1) Non-collectively bargained plans. (i) Plan years commencing before September 23, 2010. A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), for plan years commencing before September 23, 2010, from any or all of the following requirements:

(A) Limitations on preexisting condition exclusion periods described in § 146.111.

(B) Special enrollment periods for individuals and dependents described in § 146.117.

(C) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements in § 146.121(a)(1)(vi) and § 146.122 that prohibit discrimination with respect to genetic information.

(D) Standards relating to benefits for mothers and newborns described in § 146.130.

(E) Parity in the application of certain limits to mental health benefits described in § 146.136.

(F) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2727 of the PHS Act.

(G) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(ii) Plan years beginning on or after September 23, 2010. (i) A sponsor of a self-funded non-Federal governmental plan may elect to exempt its plan for plan years beginning on or after September 23, 2010, only from any or all of the requirements described in paragraph (a)(1)(i)(D), (E), (F) or (G). With respect to those plan years, the notices required by paragraph (f) of this section must reflect the limitations set forth in this paragraph (a)(1)(ii).

(iii) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1)(i). The plan year commences September 1 each year. The plan is not subject to the limitations of paragraph (a)(1)(ii) until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(iv) Example 2. Same facts as in Example 1, except the plan year commences October 1 each year. The plan is subject to the limitations of paragraph (a)(1)(ii) beginning with the plan year that commences on October 1, 2010. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(2) Collectively bargained plans. (i) Special rule. Without regard to paragraph (b)(2) of this section, a group health plan that is governed by a collective bargaining agreement that was ratified before March 23, 2010, is subject to the limitations set forth in paragraph (a)(1)(ii) beginning with the commencement of the first plan year following the expiration of the last plan year governed by the collective bargaining agreement. The notices required by paragraph (f) of this section, with respect to the first plan year subject to the limitations of paragraph (a)(1)(ii), must reflect those limitations.

(ii) Example. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1)(i) of this section. The collective bargaining agreement applies to five plan years, October 1, 2007 through September 30, 2012. For the plan year that commences on October 1, 2012, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1)(i)(A), (B) and (C). Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraph (a)(1)(i)(D), (E), (F) and (G).

(3) Limitations. * * *

(A) Example 1. A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

* * *

(4) Stop-loss or excess risk coverage. For purposes of this section—(i) Subject to paragraph (a)(4)(ii), * * *

(5) Construction. * * *

* * * * *

(c) Mailing address. The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Medicare Enrollment and Appeals Group, CPC, ATTN: HIPAA Opt-Out, 7500 Security Boulevard, C2-12-16, Baltimore, MD 21244-1850. Alternatively, the plan sponsor may fax the exemption election to 410-786-8001.

* * * * *

(f) * * *

(2) * * *

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, * * *

(3) * * *

(i) The specific requirements described in paragraphs (a)(1) or (a)(2) of this section, as applicable, from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

* * * * *

(h) * * *

(4) * * *

(i) Example 1. (A) * * *

(B) * * * However, regarding plan years that begin on or after September 23, 2010, the plan sponsor no longer can elect to exempt its plan from prohibitions against enrollment discrimination based on health status-related factors.

* * *

(i) * * *

(2) * * *

(iv) Example 4: A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from the requirements of paragraph (a)(1)(i)(E) of this section. The collective bargaining agreement applies to five plan years, 2007 through 2011. For the

first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2007 through December 31, 2011. Prior to the dissemination of the annual notice for the 2010 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2007 through December 31, 2011. Accordingly, CMS would not invalidate the election for the 2010 plan year.

From: Botwinick, Alexandra (HHS/OCIIO)
Sent: Friday, September 24, 2010 4:07 PM
To: 'lhickok@bcsigroup.com'
Subject: Waiver of the Annual Limits Requirements of the PHS Act Section 2711

Attachments: OCIIO_Waiver_Acceptance_Letter.pdf

Dear Applicant,

Thank you for submitting an application for a Waiver of the Annual Limits Requirements of the PHS Act Section 2711. HHS has reviewed your application and made its determination. Please see the attached letter.

Please confirm receipt of this letter by replying to this e-mail with a copy to OCIIOoversight@hhs.gov.

Please let me know if I can be of further assistance.

Sincerely,

Alexandra Botwinick

Office of Oversight
HHS/OCIIO
alexandra.botwinick@hhs.gov

From: Hickok, Linda [lhickok@bcsgroup.com]
Sent: Wednesday, September 22, 2010 3:49 PM
To: Pham, Erica (HHS/OCIIO)
Subject: RE: Applications submission for Waiver of Annual Limits - BCS Ins Group
Signed By: lhickok@bcsgroup.com

Attachments: BCS Ins - Waiver - premium increase chart 092210.docx

Dear Ms. Pham:

I have attached an exhibit which provides the additional data that you requested.

Our actuary has pointed out that I misstated the high end of the weekly rates in my application letter. Please accept my apologies for this incorrect information. The actual current weekly rate ranges are as follows (and correctly indicated on the attached exhibit):

Employee	\$15.39 - \$65.29
Employee plus 1	\$32.37 - \$143.62
Family	\$49.31 – 228.50

Thank you –
 Linda Hickok

Linda H. Hickok, JD
Assistant Vice President, Compliance
BCS Insurance Group
phone (630) 472-7726
fax (630) 472-7822

From: Pham, Erica (HHS/OCIIO) [mailto:Erica.Pham@hhs.gov]
Sent: Tuesday, September 21, 2010 3:49 PM
To: Hickok, Linda
Cc: Andrews, Jane (HHS/OCIIO)
Subject: Applications submission for Waiver of Annual Limits - BCS Ins Group

Dear Ms. Hickock:

For the BCS Insurance Group products offered and for which you have made an application for a waiver from annual limits, you provided us with rolled up ranges for all of the plans with differing annual limits and provided only a rolled up weekly rates for the annual limits.

What we would like is for them to show us for each annual limit level within each product, what the lowest premium is and what the highest premium is. In other words, disaggregate the annual limits in accordance with their associated premiums and with the premium that would result from going to the current annual limit to \$750,000.00.

Here's an example of how we'd want to see the additional data:

<u>Product name</u>	<u>Current annual limit</u>	<u>Current premium</u>	<u>Expected premium if Annual limit=\$750,000</u>	<u>Percent increase of current premium to expected premium</u>

If under each product name they could list out the lowest and the highest premium plans and what the lowest and

highest premiums' plans associated annual limits are what is the percent increase for those lowest and highest premium plans.

Because this has policy anniversaries beginning on September 24, we need to complete our review of a complete application in the next few days. It would be great if we could have this information by tomorrow, noon (eastern).

Kind Regards,

Erica Pham
Division of Enforcement
Office of Oversight
OCIIO/HHS
301-492-4108
erica.pham@hhs.gov

From: Pham, Erica (HHS/OCIIO)
Sent: Tuesday, September 21, 2010 4:49 PM
To: 'lhickok@bcsigroup.com'
Cc: Andrews, Jane (HHS/OCIIO)
Subject: Applications submission for Waiver of Annual Limits - BCS Ins Group
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What we would like is for them to show us for each annual limit level within each product, what the lowest premium is and what the highest premium is. In other words, disaggregate the annual limits in accordance with their associated premiums and with the premium that would result from going to the current annual limit to \$750,000.00.

Here's an example of how we'd want to see the additional data:

<u>Product name</u>	<u>Current annual limit</u>	<u>Current premium</u>	<u>Expected premium if Annual limit=\$750,000</u>	<u>Percent increase of current premium to expected premium</u>

-
If under each product name they could list out the lowest and the highest premium plans and what the lowest and highest premiums' plans associated annual limits are what is the percent increase for those lowest and highest premium plans.

Because this has policy anniversaries beginning on September 24, we need to complete our review of a complete application in the next few days. It would be great if we could have this information by tomorrow, noon (eastern).

Kind Regards,

Erica Pham
Division of Enforcement
Office of Oversight
OCIIO/HHS
301-492-4108
erica.pham@hhs.gov

From: Frias, Maria [MFrias@BCSIGROUP.COM]
Sent: Monday, September 13, 2010 10:32 AM
To: HHS HealthInsurance (HHS)
Subject: BCS Insurance Company-Application for Waiver of Annual Limit

Follow Up Flag: Follow up
Flag Status: Red

Attachments: Signed Waiver Letter & Attestation.pdf

Dear Sir,

Attached please find an application Letter for Waiver of Annual Limit for the company-BCS Insurance Company.

We will also send the original hard copy of this application via overnight mail to the attention of Mr. James Mayhew.

Should you have any questions in this regard, please contact me.

Sincerely,

Maria Frias
Regulatory Analyst
BCS Insurance Group
phone (630) 472-7762
fax (630) 472-7822



BCS Life Insurance Company
BCS Insurance Company
2 Mid America Plaza, Suite 200
Oakbrook Terrace, Illinois 60181
T 630.472.7726 F 630.472.7822
lhickok@bcsgroup.com

September 13, 2010

HHS, Office of Consumer Information and Insurance Oversight
Office of Oversight
Attention James Mayhew
Room 747-F-04
200 Independence Avenue, SW
Washington, DC 20201

Re: Application for Waiver of the Annual Limits Requirements
Limited Benefit Plans (Form 24.220)
Insured by BCS Insurance Company, NAIC 38245

Dear Mr. Mayhew:

BCS Insurance Company hereby makes application for its currently issued limited benefit medical expense group policies and requests that the Department of Health and Human Services grants these plans a waiver of the annual limits requirements of PHS Act Section 2711 for the upcoming plan year.

1. BCS Insurance Company insures group limited benefit medical expense policies issued to employers for coverage of hourly paid and part time employees. These policies have been in effect prior to September 23, 2010. The policy anniversaries of these plans are staggered over the next 12 months beginning on September 24, 2010.
2. There are currently 115,000 employees covered under this plan.
3. We provide each employer policyholder with a selection of several coverage levels for their group limited medical benefit plan. The ranges of these annual plan limits and rates are outlined below:

Annual maximum (combined inpatient and outpatient benefits)	\$2000 - \$50,000
Inpatient Maximums	
• Daily Room & Board	\$200 - no daily limit
• Daily ICU	\$400 - no daily limit
• Annual Inpatient Miscellaneous	\$1000 – no daily limit
Outpatient Annual Maximum	\$1500 – no daily limit
Prescription Drug Maximum	\$50 monthly - \$3000 annual

Application for Waiver of Annual Limits
BCS Insurance Company
Page 2

Weekly Rates

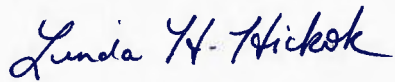
Employee	\$15.39 - \$ 50.22
Employee plus 1	\$32.37 - \$110.48
Family	\$49.31 - \$175.77

4. Compliance with the interim final regulations would result in a significant increase in premiums paid by those covered by these policies. The individuals currently covered by our limited benefit plans are lower paid hourly or part time workers that are not eligible for their employer's comprehensive major medical plan. These plans are a voluntary purchase medical product with usually no employer subsidy. If the annual maximum is raised to \$750,000 per year the premiums would need to be 5 times our current limited benefit rates. This rate adjustment is based on our own company experience and the Milliman Health Cost Guidelines.
5. The required Attestation by the BCS Insurance Company Chief Executive Officer is attached.

This Application is being sent via email (healthinsurance@hhs.gov) and by overnight mail.

We respectfully request your approval of this application for waiver.

Very truly yours,



Linda H. Hickok, JD
Assistant Vice President, Compliance

BCS Insurance Company
Oakbrook Terrace, Illinois

ATTESTATION

I, Scott Beacham, President and Chief Executive Officer of BCS Insurance Company hereby certify that:

- a) the limited benefit policies issued by BCS Insurance Company were in force prior to September 23, 2010; and
- b) the application of restricted annual limits to such policies would result in a significant increase in premiums paid by those covered by such policies.

Signed this 13th day of September, 2010.



Scott Beacham
President and Chief Executive Officer

From: Hickok, Linda [lhickok@bcsgroup.com]
Sent: Friday, September 24, 2010 5:07 PM
To: Botwinick, Alexandra (HHS/OCIIO)
Cc: OCIIO Oversight
Subject: RE: Waiver of the Annual Limits Requirements of the PHS Act Section 2711
Signed By: lhickok@bcsgroup.com

Follow Up Flag: Follow up

Flag Status: Blue

Ms. Botwinick – this is to confirm receipt of your email and attached letter granting waiver of annual limits to BCS Insurance Company. Thank you – Linda Hickok

Linda H. Hickok, JD
Assistant Vice President, Compliance
BCS Insurance Group
phone (630) 472-7726
fax (630) 472-7822

From: Botwinick, Alexandra (HHS/OCIIO) [mailto:Alexandra.Botwinick@hhs.gov]
Sent: Friday, September 24, 2010 3:07 PM
To: Hickok, Linda
Subject: Waiver of the Annual Limits Requirements of the PHS Act Section 2711

Dear Applicant,

Thank you for submitting an application for a Waiver of the Annual Limits Requirements of the PHS Act Section 2711. HHS has reviewed your application and made its determination. Please see the attached letter.

Please confirm receipt of this letter by replying to this e-mail with a copy to OCIIOoversight@hhs.gov.

Please let me know if I can be of further assistance.

Sincerely,

Alexandra Botwinick

Office of Oversight
HHS/OCIIO
alexandra.botwinick@hhs.gov

From: [Larsen, Steven \(HHS/OCIIO\)](#)
To: [Gaston-Hawkins, Lauren \(HHS/OCIIO\)](#)
Cc: [Andrews, Jane \(HHS/OCIIO\)](#)
Subject: FOIA McDonald's
Date: Wednesday, November 03, 2010 8:35:16 AM

-----Original Message-----

From: Larsen, Steven (HHS/OCIIO)
Sent: Wednesday, September 29, 2010 8:18 AM
To: 'Mark.Iwry@do.treas.gov'; 'dave.carroll@us.mcd.com'
Subject: RE: MLR - Discussion with McDonald's and BCS

Ok - Dave can we use the same call in?

-----Original Message-----

From: Mark.Iwry@do.treas.gov [<mailto:Mark.Iwry@do.treas.gov>]
Sent: Tuesday, September 28, 2010 11:50 PM
To: Larsen, Steven (HHS/OCIIO); dave.carroll@us.mcd.com
Subject: Re: MLR - Discussion with McDonald's and BCS

Yes, thanks.

J. Mark Iwry
Special Advisor to the Secretary
Deputy Assistant Secretary for
Retirement and Health Policy
U.S. Department of the Treasury
(202) 622 7827
mark.iwry@do.treas.gov

----- Original Message -----

From: Larsen, Steven (HHS/OCIIO) <Steven.Larsen@hhs.gov>
To: 'Dave.Carroll@us.mcd.com' <Dave.Carroll@us.mcd.com>
Cc: Iwry, Mark
Sent: Tue Sep 28 23:25:50 2010
Subject: Re: MLR - Discussion with McDonald's and BCS

Works for me - mark, let us know if you are available also.

From: Carroll Dave [<mailto:Dave.Carroll@us.mcd.com>]
Sent: Tuesday, September 28, 2010 09:43 PM
To: Larsen, Steven (HHS/OCIIO)
Cc: 'Mark.Iwry@do.treas.gov' <Mark.Iwry@do.treas.gov>
Subject: RE: MLR - Discussion with McDonald's and BCS

Steve - Thanks for your note. How about 2:30pm EST on Wed? Let me know if that works. If so, call-in detail is noted below. Thanks, Dave

Tel #: 1.800.508.7631
Mtg #: *2892242* (don't forget asterisks around number)

From: Larsen, Steven (HHS/OCIIO) [<mailto:Steven.Larsen@hhs.gov>]
Sent: Tuesday, September 28, 2010 1:21 PM
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Subject: RE: MLR - Discussion with McDonald's and BCS

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Gaston-Hawkins, Lauren (HHS/OCIO)

From: Larsen, Steven (HHS/OCIO)
Sent: Wednesday, November 03, 2010 8:35 AM
To: Gaston-Hawkins, Lauren (HHS/OCIO)
Cc: Andrews, Jane (HHS/OCIO)
Subject: FOIA McDonald's

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Orange Category

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Sent: Wednesday, September 29, 2010 8:18 AM
To: 'Mark.Iwry@do.treas.gov'; 'dave.carroll@us.mcd.com'
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Gaston-Hawkins, Lauren (HHS/OCIIO)

From: Larsen, Steven (HHS/OCIIO)
Sent: Wednesday, November 03, 2010 8:33 AM
To: Gaston-Hawkins, Lauren (HHS/OCIIO)
Cc: Andrews, Jane (HHS/OCIIO)
Subject: FOIA McDonald's

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Orange Category

From: Larsen, Steven (HHS/OCIIO)
Sent: Tuesday, September 28, 2010 11:26 PM
To: 'Dave.Carroll@us.mcd.com'
Cc: 'Mark.Iwry@do.treas.gov'
Subject: Re: MLR - Discussion with McDonald's and BCS

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Gaston-Hawkins, Lauren (HHS/OCIIO)

From: Larsen, Steven (HHS/OCIIO)
Sent: Wednesday, November 03, 2010 8:32 AM
To: Gaston-Hawkins, Lauren (HHS/OCIIO)
Cc: Andrews, Jane (HHS/OCIIO)
Subject: FOIA McDonald's

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Orange Category

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Sent: Tuesday, September 28, 2010 2:21 PM
To: 'Carroll Dave'
Cc: 'Mark.Iwry@do.treas.gov'
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From: Carroll Dave [\[mailto:Dave.Carroll@us.mcd.com\]](mailto:Dave.Carroll@us.mcd.com)
Sent: Tuesday, September 28, 2010 10:17 AM
To: Larsen, Steven (HHS/OCIIO)
Subject: RE: MLR - Discussion with McDonald's and BCS

Steve - We have everyone set for 10:20 EST. We can use our conference call number: 1.800.508.7631, then meeting number *2892242* (don't forget asterisks around number). Let me know if this will still work out for you. Thanks, Dave

From: Larsen, Steven (HHS/OCIIO) [\[mailto:Steven.Larsen@hhs.gov\]](mailto:Steven.Larsen@hhs.gov)
Sent: Tuesday, September 28, 2010 8:00 AM
To: Carroll Dave
Subject: RE: MLR - Discussion with McDonald's and BCS

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From: Carroll Dave [\[mailto:Dave.Carroll@us.mcd.com\]](mailto:Dave.Carroll@us.mcd.com)
Sent: Tuesday, September 28, 2010 8:58 AM
To: Larsen, Steven (HHS/OCIIO)
Subject: RE: MLR - Discussion with McDonald's and BCS

Steve - Thanks for your note. I'm checking with our carrier to see if we can make this morning work. I'll get back to you shortly. Thanks, Dave

From: Larsen, Steven (HHS/OCIIO) [\[mailto:Steven.Larsen@hhs.gov\]](mailto:Steven.Larsen@hhs.gov)
Sent: Monday, September 27, 2010 7:07 PM
To: Carroll Dave
Cc: 'Mark.Iwry@do.treas.gov'
Subject: RE: MLR - Discussion with McDonald's and BCS

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Gaston-Hawkins, Lauren (HHS/OCIIO)

From: Larsen, Steven (HHS/OCIIO)
Sent: Wednesday, November 03, 2010 8:31 AM
To: Gaston-Hawkins, Lauren (HHS/OCIIO)
Cc: Andrews, Jane (HHS/OCIIO)
Subject: FOIA McDonald's

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Orange Category

From: Larsen, Steven (HHS/OCIIO)
Sent: Tuesday, September 28, 2010 10:28 AM
To: 'Carroll Dave'
Subject: RE: MLR - Discussion with McDonald's and BCS

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Subject: FOIA McDonalds

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Green Category

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Subject: RE: MLR - Discussion with McDonald's and BCS

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Gaston-Hawkins, Lauren (HHS/OCIIO)

From: Larsen, Steven (HHS/OCIIO)
Sent: Wednesday, November 03, 2010 8:29 AM
To: Gaston-Hawkins, Lauren (HHS/OCIIO)
Cc: Andrews, Jane (HHS/OCIIO)
Subject: FOIA - McDonalds

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Orange Category

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From: Carroll Dave [<mailto:dave.carroll@us.mcd.com>]
Sent: Friday, September 24, 2010 6:08 PM
To: Larsen, Steven (HHS/OCIIO)
Cc: Mark.Iwry@do.treas.gov
Subject: MLR - Discussion with McDonald's and BCS

Mr. Larsen,

I hope all is well. I spoke earlier today with Mark Iwry at Treasury who advised that you would be willing to talk with McDonald's and BCS (our limited benefit carrier) to discuss our challenges regarding MLR. We would greatly appreciate that opportunity. McDonald's and BCS can make ourselves available anytime on Monday, September 27. If that would work for you, please advise of a time that would be convenient. Again, thank you for the opportunity. We look forward to talking soon.

Take care,

Dave Carroll
Senior Director, U.S. Benefits & Compensation
McDonald's USA LLC
tel: 630.623.6028
email: dave.carroll@us.mcd.com

From: Carroll Dave
Sent: Thursday, September 23, 2010 5:22 PM
To: 'Steven.Larsen@hhs.gov'
Cc: Bryant Bo
Subject: MLR - Note from McDonald's USA

Dear Mr. Larsen,

My name is Dave Carroll from the U.S. Benefits & Compensation group at McDonald's USA LLC. Paul Dennet from ABC suggested I contact you regarding the pending regulatory guidance on the minimum loss ratio. As your team prepares the forthcoming regulations, I thought it might be helpful to share some of our challenges with the MLR in relation to our current limited benefit plan. Being respectful of your time, I'll keep this brief.

Beyond the corporate entity, McDonald's USA consists of over 2,400 independent owner/operators. Our company and its franchisees have been offering a fully insured limited benefit plan to its hourly restaurant employees for over 10 years. In addition to the corporate entity, we currently have over 2,000 franchisees offering the plan – spanning across more than 10,500 restaurants.

We strongly believe we have one of the highest quality limited benefit plans available in the marketplace – including a customized medical plan providing outpatient, inpatient, preventive care, and prescription drug coverage. In the interests of the health and wellbeing of our employees, we've aggressively promoted the value of health insurance, and, as a result, have significantly grown participation in the program. Currently, we have about 29,500 employees enrolled for medical coverage within our limited benefit plan. With 85% of our participants having less than \$5,000 in medical expenses per year, our limited benefit plan represents a valued and affordable insurance option.

We have been informed by our insurance carrier that, to continue to offer this valuable and affordable plan to our employees, our carrier would need to receive both an annual limit waiver and an exemption from the minimum loss ratio. Our carrier has submitted an Application for Waiver of the Annual Limits Requirements to the HHS per the guidelines released in September. We are hopeful that the waiver will be granted. However, our understanding is that, considering the low premium rates of limited benefit plans in comparison to administrative costs, it would be economically prohibitive for our carrier to continue offering the plan unless an MLR exemption was granted.

Having to drop our current mini-med offering would represent a huge disruption to our 29,500 participants. Most troubling is that it would deny our people this current benefit that positively impacts their lives and protects their health - and would leave many without an affordable, comparably designed alternative until 2014. Therefore, an MLR exemption will be essential in the interests of preserving what our employees have today and ensuring a bridge to a newly defined marketplace in 2014. In addition, receiving guidance quickly will be equally critical so as to prepare appropriately for our open enrollment period in November.

If you feel it would be of value, I am certainly available to further discuss the above with you. I know that our carrier (BCS Financial) sent a letter on September 22 to you directly to represent their perspective. I'd be happy to forward a copy of that to you if you have not yet received it.

Thank you for your time.

Take care,

Dave Carroll
Senior Director, U.S. Benefits & Compensation
McDonald's USA LLC
tel: 630.623.6028
email: dave.carroll@us.mcd.com

Real, Francis (HHS/ASPA)

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Sent: Wednesday, November 03, 2010 8:35 AM
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Cc: Andrews, Jane (HHS/OCIO)
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Eckert, Robert (HHS/ASPA)

From: Chao, Henry (HHS/OCIO)
Sent: Friday, October 01, 2010 1:07 PM
To: Thompson, Penny R. (CMS/CMSO); 'Garza Gina'
Cc: Delew, Nancy (HHS/OCIO); Ario, Joel (HHS/OCIO); Lumsden, Susan (HHS/OCIO); Lorsbach, Michael (HHS/OCIO); Kane, Terence (HHS/OCIO); Laverdiere, Donna (HHS/OCIO); Skura, Carrie (HHS/OCIO); Outerbridge, Monique (HHS/OCIO); Buchele, Libbie (HHS/OCIO); Files Flory, Ashley (HHS/ASPE/HP); Coy, Curtis (HHS/OCIO); Strollo, Michelle (HHS/OCIO); Feagins, Michelle (HHS/OCIO); Fowler, Liz (HHS/OCIO); Smith, Barbara (HHS/OCIO); Brooks-LaSure, Chiquita (HHS/OHR); Kelley, Curtis (HHS/ASFR); Sandoe, Emma (HHS/ASFR); Stafford, Leslie (HHS/OGC)
Subject: Requesting IRS and CMS comments on Draft FOA for Exchange IT
Attachments: Exchange_IT_Prototype_FOA_v5.doc
Importance: High

Penny and Gina,

Per our discussion at the IRS-HHS Coordinating Committee yesterday, attached is the Draft Funding Opportunity Announcement for the purposes of working with states to accelerate the IT work for Exchanges and allow the states that are in a higher state of readiness to get started as soon as possible and to also share their deliverables with other states. I indicated OCIO would share this draft so we can get your comments earlier rather than go through additional versions and then sending it out to you both, which would cause unnecessary delays in meeting our stated goal of publishing the FOA by 10/22.

Internally we will continue to refine some of the placeholder areas and content relating to the structure of the FOA. We really need your comments to focus on the areas in the FOA focused on IT such as the principles, core functions, required activities and due dates, etc. and provide us with suggestions on how to best incorporate the appropriate elements and level of detail from the ConOps work and the draft IT Guidance Outline document we reviewed at last week's working group meeting.

Please return your comments back to us by noon, Tuesday October 5th and send them to all of the following people:

susan.lumsden@hhs.gov
terence.kane@hhs.gov
carrie.skura@hhs.gov
michael.lorsbach@hhs.gov
donna.laverdiere@hhs.gov
henry.chao@hhs.gov

If you have any questions, please feel free to contact me.

Henry Chao
Chief Information Officer
Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
7501 Wisconsin Ave.
Bethesda, MD 20814
301-492-4100 (Main)
301-492-4456 (Direct)

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW:

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Eckert, Robert (HHS/ASPA)

From: Montgomery, Cynthia (HHS/OCIIO)
Sent: Wednesday, October 13, 2010 6:04 PM
To: Cohen, Ken ES (HHS/OCIIO); Gurule, Roman (HHS/OCIIO)
Cc: Kane, Terence (HHS/OCIIO); Buchele, Libbie (HHS/OCIIO); Feagins, Michelle (HHS/OCIIO); Files Flory, Ashley (HHS/ASPE/HP)
Subject: FW: FOA for OCIIO Clearance, Innovative Exchange
Attachments: Exchange_IT_Prototype_FOA_v14.doc

Importance: High

Greetings,

Attached is the draft Funding Opportunity Announcement for "Cooperative Agreements to Support Innovative Exchange Information Technology Systems" for OCIIO review and clearance. Please return all comments back to me by 10:00 am Thursday, Oct 14, 2010. Thank you!

Cynthia R. Montgomery, MPA
Chief Grants Management Officer
Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
7501 Wisconsin Ave.
Bethesda, MD 20814

Direct: 301-492-4309
Mobile: 202-641-0690

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Eckert, Robert (HHS/ASPA)

From: McDonough, Aisling (HHS/OCIO)
Sent: Friday, October 01, 2010 3:48 PM
To: Angoff, Jay (HHS/OCIO); Fowler, Liz (HHS/OCIO); Coy, Curtis (HHS/OCIO); Files Flory, Ashley (HHS/ASPE/HP); Chao, Henry (HHS/CMS); Ario, Joel (HHS/OCIO); Pollitz, Karen (HHS/OCIO); Popper, Richard (HHS/OCIO); Larsen, Steven (HHS/OCIO); OS CMSD-CMS Correspondence (HHS/OGC); Mills, Marsha (HHS/OCIO); Drobac, Krista (HHS/OCIO); Wilson, Lisa (HHS/OCIO)
Cc: Cohen, Ken ES (HHS/OCIO); Gurule, Roman (HHS/OCIO); Lipscomb, Darla (HHS/OCIO); Venson, Shelby (HHS/OCIO); Underwood, Lauren (HHS/IOS); Hill, Jamaa (HHS/OCIO); OCIO ExecSec; Martin, Patrick (HHS/OCIO); Blodgett, Bennett (HHS/OCIO); Skura, Carrie (HHS/OCIO); O'Brien, Kelly (HHS/OCIO); Sutton, Erin (HHS/OCIO); Gotts, Jill (HHS/OCIO); Ahlstrom, Alexis (HHS/OCIO); Fisher, Barbara (HHS/OGC)
Subject: Clearance COB Wed. 10/6: OCIO Website Overhaul
Attachments: OCIO Website Update.doc
Importance: High

Attached is External Affairs' proposal to overhaul the OCIO website. It includes recommendations as well as an outline for the information architecture. Your comment or clearance is due by COB Wednesday, October 6. Once the proposal clears OCIO, it will be submitted for Departmental clearance.

Thank you for your help.

Aisling McDonough
Policy Coordinator and Correspondence Manager
Executive Secretariat & Regulatory Affairs
Office of Consumer Information & Insurance Oversight
Department of Health & Human Services

Washington, DC: (202) 260-6081
Bethesda: (301)492-4276

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Reali, Francis (HHS/ASPA)

From: Larsen, Steven (HHS/OCIIO)
Sent: Monday, July 19, 2010 6:53 PM
To: Cohen, Gary (HHS/OCIIO); Mayhew, James A. (CMS/CPC); Ahlstrom, Alexis (HHS/OCIIO)
Subject: Limited benefit plans

From: Andrea LaRue [<mailto:alarue@nvglc.com>]
Sent: Monday, July 19, 2010 6:39 PM
To: Larsen, Steven (HHS/OCIIO)
Subject: referral from sam mitchell

Hello Steven – I got sent to you by Sam in the Secretary's office because I trying to understand the timeline for guidance on Limited Benefit Plans and the waiver process for the new annual dollar limits. I have worked with the United Farm Workers for years and their plan for workers will clearly need to go through this process. They are trying to plan for when they need to be active as they have many employer partners that will need to be part of the process. Thank you so much for any assistance you can provide.

Andrea LaRue
Partner
NVG, LLC
www.nvglc.com
202-778-0740

Real, Francis (HHS/ASPA)

From: Larsen, Steven (HHS/OCIO)
Sent: Wednesday, November 03, 2010 8:35 AM
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Subject: RE: MLR - Discussion with McDonald's and BCS

Ok - Dave can we use the same call in?

-----Original Message-----

From: Mark.Iwry@do.treas.gov [<mailto:Mark.Iwry@do.treas.gov>]
Sent: Tuesday, September 28, 2010 11:50 PM
To: Larsen, Steven (HHS/OCIO); dave.carroll@us.mcd.com
Subject: Re: MLR - Discussion with McDonald's and BCS

Yes, thanks.

J. Mark Iwry
Special Advisor to the Secretary
Deputy Assistant Secretary for
Retirement and Health Policy
U.S. Department of the Treasury
(202) 622 7827
mark.iwry@do.treas.gov

----- Original Message -----

From: Larsen, Steven (HHS/OCIO) <Steven.Larsen@hhs.gov>
To: 'Dave.Carroll@us.mcd.com' <Dave.Carroll@us.mcd.com>
Cc: Iwry, Mark
Sent: Tue Sep 28 23:25:50 2010
Subject: Re: MLR - Discussion with McDonald's and BCS

Works for me - mark, let us know if you are available also.

From: Carroll Dave [<mailto:Dave.Carroll@us.mcd.com>]
Sent: Tuesday, September 28, 2010 09:43 PM
To: Larsen, Steven (HHS/OCIO)
Cc: 'Mark.Iwry@do.treas.gov' <Mark.Iwry@do.treas.gov>
Subject: RE: MLR - Discussion with McDonald's and BCS

Steve - Thanks for your note. How about 2:30pm EST on Wed? Let me know if that works. If so, call-in detail is noted below. Thanks, Dave

Tel #: 1.800.508.7631

Mtg #: *2892242* (don't forget asterisks around number)

From: Larsen, Steven (HHS/OCIO) [<mailto:Steven.Larsen@hhs.gov>]

Sent: Tuesday, September 28, 2010 1:21 PM

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Cc: 'Mark.Iwry@do.treas.gov'

Subject: RE: MLR - Discussion with McDonald's and BCS

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From: Chao, Henry (HHS/OCIO)
Sent: Friday, October 01, 2010 1:07 PM
To: Thompson, Penny R. (CMS/CMSO); 'Garza Gina'
Cc: Delew, Nancy (HHS/OCIO); Ario, Joel (HHS/OCIO); Lumsden, Susan (HHS/OCIO); Lorsbach, Michael (HHS/OCIO); Kane, Terence (HHS/OCIO); Laverdiere, Donna (HHS/OCIO); Skura, Carrie (HHS/OCIO); Outerbridge, Monique (HHS/OCIO); Buchele, Libbie (HHS/OCIO); Files Flory, Ashley (HHS/ASPE/HP); Coy, Curtis (HHS/OCIO); Strollo, Michelle (HHS/OCIO); Feagins, Michelle (HHS/OCIO); Fowler, Liz (HHS/OCIO); Smith, Barbara (HHS/OCIO); Brooks-LaSure, Chiquita (HHS/OHR); Kelley, Curtis (HHS/ASFR); Sandoe, Emma (HHS/ASFR); Stafford, Leslie (HHS/OGC)
Subject: Requesting IRS and CMS comments on Draft FOA for Exchange IT
Attachments: Exchange_IT_Prototype_FOA_v5.doc
Importance: High

Penny and Gina,

Per our discussion at the IRS-HHS Coordinating Committee yesterday, attached is the Draft Funding Opportunity Announcement for the purposes of working with states to accelerate the IT work for Exchanges and allow the states that are in a higher state of readiness to get started as soon as possible and to also share their deliverables with other states. I indicated OCIO would share this draft so we can get your comments earlier rather than go through additional versions and then sending it out to you both, which would cause unnecessary delays in meeting our stated goal of publishing the FOA by 10/22.

Internally we will continue to refine some of the placeholder areas and content relating to the structure of the FOA. We really need your comments to focus on the areas in the FOA focused on IT such as the principles, core functions, required activities and due dates, etc. and provide us with suggestions on how to best incorporate the appropriate elements and level of detail from the ConOps work and the draft IT Guidance Outline document we reviewed at last week's working group meeting.

Please return your comments back to us by noon, Tuesday October 5th and send them to all of the following people:

susan.lumsden@hhs.gov
terence.kane@hhs.gov
carrie.skura@hhs.gov
michael.lorsbach@hhs.gov
donna.laverdiere@hhs.gov
henry.chao@hhs.gov

If you have any questions, please feel free to contact me.

Henry Chao
Chief Information Officer
Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
7501 Wisconsin Ave.
Bethesda, MD 20814
301-492-4100 (Main)
301-492-4456 (Direct)

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Eckert, Robert (HHS/ASPA)

From: Montgomery, Cynthia (HHS/OCIIO)
Sent: Wednesday, October 13, 2010 6:04 PM
To: Cohen, Ken ES (HHS/OCIIO); Gurule, Roman (HHS/OCIIO)
Cc: Kane, Terence (HHS/OCIIO); Buchele, Libbie (HHS/OCIIO); Feagins, Michelle (HHS/OCIIO); Files Flory, Ashley (HHS/ASPE/HP)
Subject: FW: FOA for OCIIO Clearance, Innovative Exchange
Attachments: Exchange_IT_Prototype_FOA_v14.doc

Importance: High

Greetings,

Attached is the draft Funding Opportunity Announcement for "Cooperative Agreements to Support Innovative Exchange Information Technology Systems" for OCIIO review and clearance. Please return all comments back to me by 10:00 am Thursday, Oct 14, 2010. Thank you!

Cynthia R. Montgomery, MPA

Chief Grants Management Officer
Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
7501 Wisconsin Ave.
Bethesda, MD 20814

Direct: 301-492-4309

Mobile: 202-641-0690

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From: McDonough, Aisling (HHS/OCIO)
Sent: Friday, October 01, 2010 3:48 PM
To: Angoff, Jay (HHS/OCIO); Fowler, Liz (HHS/OCIO); Coy, Curtis (HHS/OCIO); Files Flory, Ashley (HHS/ASPE/HP); Chao, Henry (HHS/CMS); Ario, Joel (HHS/OCIO); Pollitz, Karen (HHS/OCIO); Popper, Richard (HHS/OCIO); Larsen, Steven (HHS/OCIO); OS CMSD-CMS Correspondence (HHS/OGC); Mills, Marsha (HHS/OCIO); Drobac, Krista (HHS/OCIO); Wilson, Lisa (HHS/OCIO)
Cc: Cohen, Ken ES (HHS/OCIO); Gurule, Roman (HHS/OCIO); Lipscomb, Darla (HHS/OCIO); Venson, Shelby (HHS/OCIO); Underwood, Lauren (HHS/IOS); Hill, Jamaa (HHS/OCIO); OCIO ExecSec; Martin, Patrick (HHS/OCIO); Blodgett, Bennett (HHS/OCIO); Skura, Carrie (HHS/OCIO); O'Brien, Kelly (HHS/OCIO); Sutton, Erin (HHS/OCIO); Gotts, Jill (HHS/OCIO); Ahlstrom, Alexis (HHS/OCIO); Fisher, Barbara (HHS/OGC)
Subject: Clearance COB Wed. 10/6: OCIO Website Overhaul
Attachments: OCIO Website Update.doc
Importance: High

Attached is External Affairs' proposal to overhaul the OCIO website. It includes recommendations as well as an outline for the information architecture. Your comment or clearance is due by COB Wednesday, October 6. Once the proposal clears OCIO, it will be submitted for Departmental clearance.

Thank you for your help.

Aisling McDonough
Policy Coordinator and Correspondence Manager
Executive Secretariat & Regulatory Affairs
Office of Consumer Information & Insurance Oversight
Department of Health & Human Services

Washington, DC: (202) 260-6081
Bethesda: (301)492-4276

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Eckert, Robert (HHS/ASPA)

From: Cohen, Ken ES (HHS/OCIIO)
Sent: Friday, September 17, 2010 8:10 PM
To: Gurule, Roman (HHS/OCIIO)
Cc: Files Flory, Ashley (HHS/ASPE/HP)
Subject: Fw: Current Status
Attachments: Options memo draft 09172010.doc; 2011 spend plan tables - draft.xls; FY 2011 Spend Plan Template - exchange-revised.doc; FY 2011 Spend Plan Template - IT resources.doc; FY 2011 Spend Plan Template - OCS - revised 2.doc; FY 2011 Spend Plan Template - oversight_revised.doc; FY 2011 Spend Plan Template - admin - revised.doc

We will approve comp time for Darla.

From: Lipscomb, Darla (HHS/OCIIO)
Sent: Friday, September 17, 2010 07:40 PM
To: Buchele, Libbie (HHS/OCIIO)
Cc: Cohen, Ken ES (HHS/OCIIO); Gurule, Roman (HHS/OCIIO)
Subject: Current Status

I am attaching

- spend plans as they currently exist
- a spend plan (table only) for IT – Monique is reviewing all submitted plans to fully assess the IT story
- current summary of the doomsday scenarios (options memo)
 - *Note that Oversight has not yet submitted theirs. Alexia has been directed to forward to both you and I when complete*
- Excel spreadsheet of the tables to support the spend plans

I have my laptop. Let me know if you need me to work on anything over the weekend.

Darla Lipscomb
Policy Coordinator
Executive Secretariat and Regulatory Affairs
Office of Consumer Information and Insurance Oversight
Tel: 301-492-4284

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Reali, Francis (HHS/ASPA)

From: Larsen, Steven (HHS/OCIO)
Sent: Wednesday, November 03, 2010 8:35 AM
To: Gaston-Hawkins, Lauren (HHS/OCIO)
Cc: Andrews, Jane (HHS/OCIO)
Subject: FOIA McDonald's

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Orange Category

-----Original Message-----

From: Larsen, Steven (HHS/OCIO)
Sent: Wednesday, September 29, 2010 8:18 AM
To: 'Mark.Iwry@do.treas.gov'; 'dave.carroll@us.mcd.com'
Subject: RE: MLR - Discussion with McDonald's and BCS

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Subject: Re: MLR - Discussion with McDonald's and BCS

Yes, thanks.

J. Mark Iwry
Special Advisor to the Secretary
Deputy Assistant Secretary for
Retirement and Health Policy
U.S. Department of the Treasury
(202) 622 7827
mark.iwry@do.treas.gov

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carrie.skura@hhs.gov
michael.lorsbach@hhs.gov
donna.laverdiere@hhs.gov
henry.chao@hhs.gov

If you have any questions, please feel free to contact me.

Henry Chao
Chief Information Officer
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Executive Secretariat & Regulatory Affairs
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BCS Insurance Company

Exhibit - Waiver of Annual Limits Application

Product Name	Lowest Plan	Lowest Weekly Rate	Expected Weekly Rate	Rate Increase	Highest Plan	Highest Weekly Rate	Expected Weekly Rate at \$750K	Rate Increase
Essential StaffCare	5K Annual Max. – EE				50K Annual Max. – EE			
	5K Annual Max. – EE+1				50K Annual Max. – EE+1			
	5K Annual Max. –				50K Annual Max. –			
Essential Care	EE+Family				EE+Family			
	2K Annual Max. – EE				15K Annual Max. – EE			
	2K Annual Max. – EE+1				15K Annual Max. – EE+1			
	2K Annual Max. –				15K Annual Max. –			
	EE+Family				EE+Family			
Hospitality Care	5K Annual Max. – EE				10K Annual Max. – EE			
	5K Annual Max. – EE+1				10K Annual Max. – EE+1			
	5K Annual Max. –				10K Annual Max. –			
	EE+Family				EE+Family			

Our book of business is approximately split as follows:

Essential StaffCare:

Essential Care:

Hospitality Care:

Overall weighted rate increase =



BCS Life Insurance Company
BCS Insurance Company
2 Mid America Plaza, Suite 200
Oakbrook Terrace, Illinois 60181
T 630.472.7726 F 630.472.7822
lhickok@bcsgroup.com

September 13, 2010

HHS, Office of Consumer Information and Insurance Oversight
Office of Oversight
Attention James Mayhew
Room 747-F-04
200 Independence Avenue, SW
Washington, DC 20201

Re: Application for Waiver of the Annual Limits Requirements
Limited Benefit Plans (Form 24.220)
Insured by BCS Insurance Company, NAIC 38245

Dear Mr. Mayhew:

BCS Insurance Company hereby makes application for its currently issued limited benefit medical expense group policies and requests that the Department of Health and Human Services grants these plans a waiver of the annual limits requirements of PHS Act Section 2711 for the upcoming plan year.

1. BCS Insurance Company insures group limited benefit medical expense policies issued to employers for coverage of hourly paid and part time employees. These policies have been in effect prior to September 23, 2010. The policy anniversaries of these plans are staggered over the next 12 months beginning on September 24, 2010.
2. There are currently 115,000 employees covered under this plan.
3. We provide each employer policyholder with a selection of several coverage levels for their group limited medical benefit plan. The ranges of these annual plan limits and rates are outlined below:

Annual maximum (combined inpatient and outpatient benefits)	\$2000 - \$50,000
Inpatient Maximums	
• Daily Room & Board	\$200 - no daily limit
• Daily ICU	\$400 - no daily limit
• Annual Inpatient Miscellaneous	\$1000 – no daily limit
Outpatient Annual Maximum	\$1500 – no daily limit
Prescription Drug Maximum	\$50 monthly - \$3000 annual

Application for Waiver of Annual Limits
BCS Insurance Company
Page 2

Weekly Rates

Employee	\$15.39 - \$ 50.22
Employee plus 1	\$32.37 - \$110.48
Family	\$49.31 - \$175.77

4. Compliance with the interim final regulations would result in a significant increase in premiums paid by those covered by these policies. The individuals currently covered by our limited benefit plans are lower paid hourly or part time workers that are not eligible for their employer's comprehensive major medical plan. These plans are a voluntary purchase medical product with usually no employer subsidy. If the annual maximum is raised to \$750,000 per year the premiums would need to be 5 times our current limited benefit rates. This rate adjustment is based on our own company experience and the Milliman Health Cost Guidelines.
5. The required Attestation by the BCS Insurance Company Chief Executive Officer is attached.

This Application is being sent via email (healthinsurance@hhs.gov) and by overnight mail.

We respectfully request your approval of this application for waiver.

Very truly yours,



Linda H. Hickok, JD
Assistant Vice President, Compliance

BCS Insurance Company
Oakbrook Terrace, Illinois

ATTESTATION

I, Scott Beacham, President and Chief Executive Officer of BCS Insurance Company hereby certify that:

- a) the limited benefit policies issued by BCS Insurance Company were in force prior to September 23, 2010; and
- b) the application of restricted annual limits to such policies would result in a significant increase in premiums paid by those covered by such policies.

Signed this 13th day of September, 2010.



Scott Beacham
President and Chief Executive Officer

The following data points were assembled in response to questions raised by HHS regarding limited benefit plans and a proposed waiver process.

1. Insurers by name who will approach HHS about a waiver:

Carrier	Typical Funding Arr.	Annual Covered Lives Estimate
Reliance	Fully Insured	120k
BCS	Fully Insured	250k
Starbridge (CIGNA)	Fully Insured	490k
United	Self and Fully Insured	200k
SRC (Aetna)	Fully Insured	450k
American Heritage/ AllState Workplace	Fully Insured	100k
Blue Cross (regional)	Self Insured	1 Million

2. Total size of the limited benefit market

The total insured marketplace between fully insured and self insured plans is around 2.5 million with approximately 1.4 million under fully insured plans and 1 million in self insured plans. The one million self insured plans are likely spread among a handful of carriers and approximately thirty administrators. Creating a waiver process at the insurer level will result in the 6 carriers above working with HHS on the waiver versus a plan level waiver process which would result in thousands of applicants.

3a. The number of employer sponsors by size band (Aetna)

Eligible tier	Total Clients	Total Eligible base
>500	946	126,893
500-999	130	85,194
1k-3k	140	237,965
3k+	125	1,697,274
Grand Total	1,341	2,147,326

Aetna Segment Definition	Aetna Segment	Total Clients	Total Eligible base
1-50 ees	Small Group (SG)	398	51,364
51-300 ees	Select (SEL)	532	158,496
301-3000 ees	Key (KEY)	296	606,696
3001+ ees	National (NA)	115	1,330,770
	Grand Total	1,341	2,147,326

3b. CIGNA Voluntary Est. Groups/Gross Membership by Plan Series (Data as of 4/30/10)

Plan Series	Est. Group Totals	Est. Gross Membership
Legacy	450	85,000
170 Series	150	91,000
370 Series	1100	105,000
	1700	281,000

4. Sample of the benefit package

The first two benefit summaries represent Aetna's two major limited benefit plan designs, although there are some historical "one-off" designs. The third one is from Starbridge (CIGNA).

Sample SRC benefit summary	Sample SRC benefit summary	Sample Starbridge Proposal
 BasicNet benefit summary.pdf	 NetPremier benefit summary.pdf	 Starbridge Proposal 04-2010.pdf

5a. Premium numbers associated with Aetna's limited benefit medical products:

Product Family	Annual Limit	EE rate wkly	EE+1 wkly	Family wkly
Net Premier	5k	\$16 - \$30	\$41-\$75	\$50-\$108
Net Premier	10k	\$20-\$40	\$41-\$103	\$60-\$148
Net Premier	15k	\$23-\$47	\$55-\$121	\$69-\$173
Net Premier	20k	\$31-\$52	\$82-\$128	\$103-\$185
Basic Net	5k	\$14-\$27	\$32-\$68	\$41-\$98
Basic Net	10K	\$17-\$35	\$35-\$89	\$53-\$126
Basic Net	15K	\$21-\$35	\$55-\$86	\$79-\$125
Basic Net	20K	\$27-\$33	\$68-\$83	\$97-\$118

Benefit Summary documents in #4 include these products and annual limits

5b. Premium Ranges by Plan Series for CIGNA

Plan Level	Avg. Weekly Rates Employee Only	Rate Range
Legacy:		
Level 1	\$9.74	\$8.05 - \$12.83
Level 2	\$18.08	\$13.60 - \$23.71
Level 3	\$27.64	\$23.35 - \$36.52
170 Series:		
Level 1	\$11.29	\$8.65 - \$15.43
Level 2	\$22.30	\$16.91 - \$28.54
Level 3	\$34.09	\$26.06 - \$43.97
370 Series:		
Level 1	\$10.94	\$9.18 - \$14.54
Level 2	\$22.46	\$18.34 - \$29.69
Level 3	\$34.11	\$27.26 - \$44.04

6. Aetna profile of business and potential impact of health care reform in the absence of a waiver process. These demographics reflect a very similar breakdown for CIGNA.



HCR Impact on
Group Limited Benefit

7. Timing of renewal decisions with waiver guidelines

Across the Aetna book of business, 25% of plan sponsors representing 43% of total membership have a coverage effective date of January 1, so renewal discussions have already started to account for the time needed to decide on the benefits, plan and conduct. To date, four plan sponsors representing approximately 400 members have lapsed coverage due to uncertainty regarding the viability of limited benefit plans and the absence of certainty around the waiver process.

Time is of the essence with respect to limited benefit plan business. It is critical that HHS quickly publish Guidance on the Waiver Program, informing the public that a process will be in place well in time to avoid any disruption in Mid-September. To this end, HHS could issue a Notice immediately (early August) advising the public of these intentions.

By size band, 49% of large employers in the Aetna book (National Accounts segment) are having renewal discussions now in advance of a January 1 effective date, 26% of medium employers in the Aetna book (Key and Select segments) will soon have renewal discussions, and 12% of small employers in the Aetna book (Small Group segment) will soon have renewal discussions. This information is provided in the following chart:

LARGE (NA)*	August	September	October	November	December	January	February
1%	renewal		enroll		effective		
49%		renewal		enroll		effective	
5%			renewal		enroll		effective

MEDIUM (KEY and SEL)*	August	September	October	November	December	January	February
5%	renewal		enroll	effective			
6%		renewal		enroll	effective		
26%			renewal		enroll	effective	
6%				renewal		enroll	effective
SMALL (SG)*	August	September	October	November	December	January	February
7%	renewal		enroll	effective			
7%		renewal		enroll	effective		
12%			renewal		enroll	effective	
5%				renewal		enroll	effective

*% of cases within Aetna BoB for that size employer

Several of Aetna's largest customers with national reach and branch recognition representing over 40,000 members are proceeding with the renewal process assuming a waiver process will be in place. Other large national customers have not made a decision and are unsure about their plans until further details are released. And, as noted above, four plan sponsors have lapsed coverage due to uncertainty around health care reform.

Once again, it is critical that HHS quickly publish Guidance on the Waiver Program, informing the public that a process will be in place well in time to avoid any disruption in Mid-September, as well as a Notice very soon of this intent.

Anecdotal information from individual employers, associations, and brokers produced the following representative quotes:

"The large insurance broker with whom I am working reports that some of its clients are dropping limited option plans NOW. Three different cases were described to me just minutes ago – more than one thousand employees will be affected in those cases altogether. Other clients are reporting problems in obtaining quotes from carriers for

limited option plans, and still others are worried about carriers that will quote seeking onerous indemnification agreements to protect themselves. In short, the market is beginning to seize up as we speak. I will try to get this information down in digestible form for possible use with HHS."

"What we have been told is that the typical open enrollment period starts October 1 and typically ends no later than the end of the month (sometimes sooner). Because we are now already within 60 days of October 1, employers are very, very likely to be at the final stages of decisions on what they are offering for 2011, so many are already at the critical "drop dead" stage or certainly will be so by early September. This seemed to reinforce for us that we are at a very late stage in the process and that the best thing would be for the agency to announce -- as soon as they possibly can -- a straightforward set of clear criteria for obtaining a waiver. That way, even if the timetable for HHS to grant a waiver came as late as mid-September, the employer and insurer would be able to very quickly determine if they meet the HHS conditions for a waiver and could presumably proceed with confidence that they will qualify. What we think would be the most problematic is for the uncertainty over the criteria for the waivers to persist over the next 30 - 45 days since each week that now goes by will likely involve more employers reaching their own internal "drop dead" deadlines for making final decisions for the year ahead."

From: Frias, Maria [MFrias@BCSIGROUP.COM]
Sent: Monday, September 13, 2010 11:20 AM
To: HHS HealthInsurance (HHS)
Subject: WAIVER

Attachments: Signed Waiver Letter & Attestation.pdf

Dear Sir,

Attached please find an [Application Letter for Waiver of Annual Limit](#) for the company-BCS Insurance Company.

We will also send the original hard copy of this application via overnight mail to the attention of Mr. James Mayhew.

Should you have any questions in this regard, please contact me.

Sincerely,

Maria Frias
Regulatory Analyst
BCS Insurance Group
phone (630) 472-7762
fax (630) 472-7822

From: [CMS Coordination_Regs_OSORA](#)
To: [Mayhew, James A. \(CMS/CPC\)](#); [Small, Jacqueline C. \(CMS/OSORA\)](#); [Swann, Renee L. \(CMS/OEORA\)](#)
Subject: FW: Review and Clearance of OCIIIO-9994-IFC
Date: Wednesday, June 16, 2010 3:32:22 PM

From: Jones, Greg A. (CMS/OL)
Sent: Wednesday, June 16, 2010 3:27 PM
To: CMS Coordination_Regs_OSORA
Cc: Precht, Paul (CMS/OL); McWright, LAURA T. (CMS/OL); Massey, Beverly A. (CMS/OL); Harrison, Vernell M. (CMS/OL); Pettijohn, Juneous A. (CMS/OL)
Subject: RE: Review and Clearance of OCIIIO-9994-IFC

The OL C/D Group clears without comments.

From: CMS Coordination_Regs_OSORA
Sent: Wednesday, June 16, 2010 9:24 AM
To: CMS - Reg_Coordinators; CMS CMSO_REGS; Mayhew, James A. (CMS/CPC)
Cc: Parker, Lisa M. (CMS/OSORA); Swann, Renee L. (CMS/OSORA); Small, Jacqueline C. (CMS/OSORA)
Subject: Review and Clearance of OCIIIO-9994-IFC

OCIIIO-9994-IFC Interim Final Rules under the Patient Protection and Affordable Care Act Regarding Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Prohibition on Discrimination in Favor of the Highly Compensated, Patient Protections, and Non-Federal Governmental Plans

HEALTH CARE REFORM REGULATION

Clearance requested by 3:00 p.m. on June 16, 2010.

Urgency: This interim final rule is scheduled for publication on **June 21, 2010**. Therefore, it is important that we receive all clearances timely. Thank you, in advance, for your prompt response.

The subject document is attached for your review and clearance. If you are the regulations coordinator, please clear the document through all divisions in your center or office, even if your center or office is the lead policy component for the document. Please forward your responses to the **CMS Coordination_Regs_OSORA Outlook mailbox** by **3:00 p.m. on June 16, 2010**. Electronic markups should include redline and strikeouts of the additions and deletions by using the "Track Changes" feature in MS Word. If you are providing comments electronically, save your comments with your component's acronym in parentheses at the end of the file name (for example, if the component is CBC, then the file would be saved as 4069-P-Preamble(CBC).doc). It would also be helpful if you would suggest language that would respond to your comment to insert into the document.

Hard copy markups may be delivered to **Jackie Small (C5-10-25)**.

This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, prohibition on discrimination in favor of highly compensated individuals, patient protections, and non-federal governmental plans.

If you have any questions regarding submission of clearances and comments, you may contact **Jackie Small, x6-6538**. Please call **Jim Mayhew, x6-9244** for policy-related questions.

From: [Cantwell, Kathleen \(HHS\)](#)
To: [Barco, Evell J. \(CMS/OEORA\)](#); [Fultz-Mimms, Trenesha N. \(CMS/OSORA\)](#); [Cantwell, Kathleen \(HHS\)](#); [Parker, Lisa M. \(CMS/OCSO\)](#); [Converse, Daniel J. \(CMS/OSORA\)](#); [Swann, Renee L. \(CMS/OEORA\)](#); [Mayhew, James A. \(CMS/CPC\)](#); [Miller, Timothy C. \(CMS/OSORA\)](#); [Seshamani, Meena \(HHS/OHR\)](#); [Corrigan, Dara \(HHS/OHR\)](#); [Kosin, Donald \(HHS/OGC\)](#); [Smalls, Dawn \(HHS/IOS\)](#); [Kronick, Richard \(HHS/ASPE/HP\)](#); [Sheingold, Steven \(HHS/ASPE\)](#)
Cc: ["Turner, Amy - EBSA"](#); ["Weinheimer Russell E"](#); ["baum.beth@dol.gov"](#)
Subject: FW: Draft Passback: Consumer Protection IFR
Date: Thursday, June 17, 2010 10:55:44 AM
Attachments: [Combined effects discussion.docx](#)
[Pkg of 5 Omnibus 6 15 10 7PM cleanEDIT.docx](#)
[Premium Calculation Worksheet.xlsx](#)
[Updated Table of benefits 061610 \(2\).docx](#)
[Mortality Calculation Worksheet \(2\).xlsx](#)
Importance: High

Looping in the relevant HHS folks. Attached is the OMB passback.

From: Aguilar, Brenda [mailto:Brenda_Aguilar@omb.eop.gov]
Sent: Thursday, June 17, 2010 10:52 AM
To: Cantwell, Kathleen (HHS)
Cc: Maguire.Daniel@dol.gov; Turner, Amy - EBSA; Cosby, Chris - EBSA; Piacentini.Joseph@dol.gov; butikofer.james@dol.gov; Mark.Iwry@do.treas.gov; George.Bostick@do.treas.gov; Weinheimer Russell E
Subject: Draft Passback: Consumer Protection IFR

HHS/DOL/Treasury Colleagues –

Please see below and attached for EOP comments on the draft Consumer Protection Interim Final Rule for your consideration. You will find that generally, the comments suggest areas where we believe the document would benefit from additional clarity, supporting rationale, and stronger analytic basis. Where possible, we've tried to provide suggestions for how to address the issues raised. We also included a few relatively straightforward suggestions on the combined effects discussion.

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We look forward to discussing with you all at today's 2:00 conference call. Please advise if you have any questions or concerns prior to our call.

Thanks,
Brenda

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From: [Cantwell, Kathleen \(HHS\)](#)
To: [Smalls, Dawn \(HHS/IOS\)](#); [White, Jacquelyn Y. \(CMS/OSORA\)](#); [Cohen, Ken ES \(HHS/OCIIO\)](#); [Gurule, Roman \(HHS/OCIIO\)](#); [Jones, Martique S. \(CMS/OSORA\)](#); [Parker, Lisa M. \(CMS/OCISO\)](#); [Miller, Timothy C. \(CMS/OSORA\)](#); [Barco, Evell J. \(CMS/OEORA\)](#); [Fultz-Mimms, Trenesha N. \(CMS/OSORA\)](#); [Potts, Oliver \(HHS/IOS\)](#); [Converse, Daniel J. \(CMS/OSORA\)](#); [Corrigan, Dara \(HHS/OHR\)](#); [Mayhew, James A. \(CMS/CPC\)](#); [Kosin, Donald \(HHS/OGC\)](#); [Parham, William N. \(CMS/OEORA\)](#); [Swann, Renee L. \(CMS/OEORA\)](#)
Subject: FW: Consumer Protection IFR
Date: Friday, June 18, 2010 6:58:55 PM

OMB has concluded review.

From: Aguilar, Brenda [mailto:Brenda_Aguilar@omb.eop.gov]
Sent: Friday, June 18, 2010 6:51 PM
To: Aguilar, Brenda; Cantwell, Kathleen (HHS)
Cc: Maguire.Daniel@dol.gov; Turner, Amy - EBSA; Cosby, Chris - EBSA; Piacentini.Joseph@dol.gov; butikofer.james@dol.gov; Mark.Iwry@do.treas.gov; George.Bostick@do.treas.gov; Weinheimer Russell E; Kronick, Richard (HHS/ASPE/HP); Widge, Alicia T.; Fitzpatrick, Mary E.; Malanoski, Margaret A.; Helen.Morrison@do.treas.gov; Seshamani, Meena (HHS/ASPE); Sheingold, Steven (HHS/ASPE)
Subject: Consumer Protection IFR

We have concluded review of the Consumer Protection IFR. Thanks to all. Please advise on Monday morning when the rule has been sent to OFR, and anything you all hear with regard to display and publication.

Thanks,
Brenda

From: [Turner, Amy - EBSA](#)
To: [Mayhew, James A. \(CMS/CPC\)](#); [Corrigan, Dara \(HHS/OHR\)](#)
Subject: Fw: Draft Passback: Consumer Protection IFR
Date: Friday, June 18, 2010 12:30:09 PM
Importance: High

[Sent via Blackberry](#)

From: Aguilar, Brenda <Brenda_Aguilar@omb.eop.gov>
To: Aguilar, Brenda <Brenda_Aguilar@omb.eop.gov>; Cantwell, Kathleen (HHS) <kathleen.cantwell@hhs.gov>
Cc: Maguire, Daniel - EBSA; Turner, Amy - EBSA; Cosby, Chris - EBSA; Piacentini, Joseph - EBSA; Butikofer, James - EBSA; Mark.Iwry@do.treas.gov <Mark.Iwry@do.treas.gov>; George.Bostick@do.treas.gov <George.Bostick@do.treas.gov>; Weinheimer Russell E <Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV>; Widge, Alicia T. <Alicia_T._Widge@omb.eop.gov>; Fitzpatrick, Mary E. <Mary_E._Fitzpatrick@omb.eop.gov>; Malanoski, Margaret A. <Margaret_A._Malanoski@omb.eop.gov>; Helen.Morrison@do.treas.gov <Helen.Morrison@do.treas.gov>; Seshamani, Meena (HHS/ASPE) <Meena.Seshamani@hhs.gov>; Kronick, Richard (HHS/ASPE/HP) <Richard.Kronick@hhs.gov>; Sheingold, Steven (HHS/ASPE) <Steven.Sheingold@HHS.GOV>
Sent: Fri Jun 18 12:17:51 2010
Subject: RE: Draft Passback: Consumer Protection IFR

All – Using this as a general check in and follow-up.

1. Thanks so much for the responses to our comments on the NonRIA portions of the rule. Everyone was generally pleased with the changes (and even the non changes.) We did have one issue that we wanted to ask you all to explore further. We understand the time constraint and therefore if the 3 Departments are not comfortable with the suggestion, or believe that there is not sufficient time to develop consensus on it, we understand and it will not hold up our concluding review. It can be found at the bottom of the email.
2. We are also pleased with the portions of the RIA changes that we have seen. We find the responses reasonable and helpful and are unlikely to have further comment (hedging only because we still have parts missing and would like confirmation from the Departments that they are ok with our suggestions to the accounting statement/summary table.)
3. Checking in to see if you have any questions or concerns with the mortality discussion/insert that we provided this morning. Would be great if we could put that issue to bed now.
4. Quantitative benefit discussion. Understand that CEA has provided material. Wondering what the Departments' reaction is to it and the status of the revised summary benefits discussion.
5. Statement of need. We are anxious to see this and would be happy to review separately. Should be straightforward and another issue that could be quickly put to bed.

Please advise right away with any updates and especially concerns. And let me know if I got anything wrong or left something out.

Thanks,
Brenda

Non RIA Suggestion: In reference to comment b8 on p. 18 of non-RIA “Pkg of 4 Overview and Reg Text” document

This rescission prevention rule aims to prevent unjustified rescissions such as those stemming from clerical errors (e.g. typos for someone's weight), errors created by other agents handling the form, or good faith mistakes by the patient. The current language aims to prevent these forms of unjustified rescissions by limiting rescissions to cases of “fraud” and “intentional misrepresentation of material fact.” However, the addition of “intentional” and “material fact” may not fully succeed in preventing unjustified rescissions. Under the current phrasing of the rule, it will still be relatively easy for insurers to legally justify continuing many rescission practices, as many patient omissions on forms can be shown to be “intentional” in the sense that they were omitted with the patient's knowledge, even if there was no purpose on the part of the patient to mislead the insurer. In order to prevent such “gap” cases where rescissions are unjustified, but still would be permitted under the proposed rule, we suggest rephrasing the preamble and the regulatory text as outlined below. These suggestions aim to ensure that good faith errors by patients do not lead to unjustified rescissions, narrowing the scope of permissible rescissions to cases where the patient purposively misleads the insurer in bad faith.

Suggested Alternative 1:

Suggest refining current description of “fraud or intentional misrepresentation of material fact” in preamble and regulatory text in order to ensure sufficiently clarity to achieve the intended benefits of the rule.

- P. 18, last full sentence: rephrase (change in bold)
 - o “Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or **a bad faith misrepresentation of material fact intended to obscure information about the condition(s) for which the patient seeks treatment.**”
 - o Make parallel change to the same phrase in regulatory text on p. 49, p. 74, p. 98: (change/addition in bold)
 - ...unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes a **bad faith misrepresentation of material fact intended to obscure information about the condition(s) for which the patient seeks treatment, or intended to violate prohibitions in the terms of the plan or coverage.**”
- P. 18, after last full sentence, add the following:
 - o “These interim final regulations therefore understand bad faith intentional misrepresentation of material fact to exclude cases of clerical errors on patient forms, errors caused by other agents handling the form, or omissions resulting from good faith errors or misunderstandings by the patient.”

Suggested Alternative 2:

- P. 18, last full sentence: rephrase (change in bold)

- o “Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or **a bad faith**, intentional misrepresentation of material fact”
- o Make parallel change to the same phrase in regulatory text on p. 49, p. 74, p. 98: (insertions in bold)
 - ...unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes a **bad faith and** intentional misrepresentation of material fact **that is** prohibited by the terms of the plan or coverage.”
- P. 18, after last full sentence, add the following:
 - o “These interim final regulations therefore understand bad faith intentional misrepresentation of material fact to exclude cases of clerical errors on patient forms, errors caused by other agents handling the form, or omissions resulting from good faith errors or misunderstandings by the patient.”

From: Aguilar, Brenda

Sent: Friday, June 18, 2010 9:42 AM

To: Aguilar, Brenda; 'Cantwell, Kathleen (HHS)'

Cc: 'Maguire.Daniel@dol.gov'; 'Turner, Amy - EBSA'; 'Cosby, Chris - EBSA'; 'Piacentini.Joseph@dol.gov'; 'butikofer.james@dol.gov'; 'Mark.Iwry@do.treas.gov'; 'George.Bostick@do.treas.gov'; 'Weinheimer Russell E'; Widge, Alicia T.; Fitzpatrick, Mary E.; Malanoski, Margaret A.; 'Helen.Morrison@do.treas.gov'; Seshamani, Meena (HHS/ASPE); Kronick, Richard (HHS/ASPE/HP); Sheingold, Steven (HHS/ASPE)

Subject: RE: Draft Passback: Consumer Protection IFR

All –

Please see attached for the Departments’ consideration is suggested language on the potential mortality benefits of the rulemaking. Please use and adapt as you see fit and let us know if you have questions or wish to discuss.

Thanks,
Brenda

From: Aguilar, Brenda

Sent: Thursday, June 17, 2010 7:02 PM

To: Aguilar, Brenda; 'Cantwell, Kathleen (HHS)'

Cc: 'Maguire.Daniel@dol.gov'; 'Turner, Amy - EBSA'; 'Cosby, Chris - EBSA'; 'Piacentini.Joseph@dol.gov'; 'butikofer.james@dol.gov'; 'Mark.Iwry@do.treas.gov'; 'George.Bostick@do.treas.gov'; 'Weinheimer Russell E'; Widge, Alicia T.; Fitzpatrick, Mary E.; Malanoski, Margaret A.

Subject: RE: Draft Passback: Consumer Protection IFR

All – per our earlier discussion, please see attached for our suggestions to revise the summary cost/benefit table.

Thanks so much for all your help. Please let us know if you have questions and feel free to tweak.

Brenda

From: Aguilar, Brenda

Sent: Thursday, June 17, 2010 10:52 AM

To: Cantwell, Kathleen (HHS)

Cc: Maguire.Daniel@dol.gov; Turner, Amy - EBSA; Cosby, Chris - EBSA; Piacentini.Joseph@dol.gov; butikofer.james@dol.gov; Mark.Iwry@do.treas.gov; George.Bostick@do.treas.gov; Weinheimer Russell E

Subject: Draft Passback: Consumer Protection IFR

HHS/DOL/Treasury Colleagues –

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Please do what is feasible given the date and in the time we have. We are optimistic that the comments can be largely addressed in that time. To assist the Departments as they work to provide the additional quantification requested in the passback, EOP has provided several tables and worksheets. We note that a citation is pending for VSL and we will update with that shortly.

We look forward to discussing with you all at today's 2:00 conference call. Please advise if you have any questions or concerns prior to our call.

Thanks,
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1. We suggest that the Departments include additional quantitative information on the costs and benefits of the regulation, to the extent feasible given the time constraint. We made suggestions throughout the document that we hope will assist in this regard.
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Cc: ["Turner, Amy - EBSA"](#); ["Weinheimer Russell E"](#); ["baum.beth@dol.gov"](#)
Subject: FW: Draft Passback: Consumer Protection IFR
Date: Thursday, June 17, 2010 10:55:44 AM
Attachments: [Combined effects discussion.docx](#)
[Pkg of 5 Omnibus 6 15 10 7PM cleanEDIT.docx](#)
[Premium Calculation Worksheet.xlsx](#)
[Updated Table of benefits 061610 \(2\).docx](#)
[Mortality Calculation Worksheet \(2\).xlsx](#)
Importance: High

Looping in the relevant HHS folks. Attached is the OMB passback.

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Brenda

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From: [Cantwell, Kathleen \(HHS\)](#)
To: [Barco, Evell J. \(CMS/OEORA\)](#); [Fultz-Mimms, Trenesha N. \(CMS/OSORA\)](#); [Cantwell, Kathleen \(HHS\)](#); [Parker, Lisa M. \(CMS/OCSO\)](#); [Converse, Daniel J. \(CMS/OSORA\)](#); [Swann, Renee L. \(CMS/OEORA\)](#); [Mayhew, James A. \(CMS/CPC\)](#); [Miller, Timothy C. \(CMS/OSORA\)](#); [Seshamani, Meena \(HHS/OHR\)](#); [Corrigan, Dara \(HHS/OHR\)](#); [Kosin, Donald \(HHS/OGC\)](#); [Smalls, Dawn \(HHS/IOS\)](#); [Kronick, Richard \(HHS/ASPE/HP\)](#); [Sheingold, Steven \(HHS/ASPE\)](#)
Cc: ["Turner, Amy - EBSA"](#); ["Weinheimer Russell E"](#); ["baum.beth@dol.gov"](#)
Subject: FW: Draft Passback: Consumer Protection IFR
Date: Thursday, June 17, 2010 10:55:44 AM
Attachments: [Combined effects discussion.docx](#)
[Pkg of 5 Omnibus 6 15 10 7PM cleanEDIT.docx](#)
[Premium Calculation Worksheet.xlsx](#)
[Updated Table of benefits 061610 \(2\).docx](#)
[Mortality Calculation Worksheet \(2\).xlsx](#)
Importance: High

Looping in the relevant HHS folks. Attached is the OMB passback.

From: Aguilar, Brenda [mailto:Brenda_Aguilar@omb.eop.gov]
Sent: Thursday, June 17, 2010 10:52 AM
To: Cantwell, Kathleen (HHS)
Cc: Maguire.Daniel@dol.gov; Turner, Amy - EBSA; Cosby, Chris - EBSA; Piacentini.Joseph@dol.gov; butikofer.james@dol.gov; Mark.Iwry@do.treas.gov; George.Bostick@do.treas.gov; Weinheimer Russell E
Subject: Draft Passback: Consumer Protection IFR

HHS/DOL/Treasury Colleagues –

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From: [Turner, Amy - EBSA](#)
To: [Mayhew, James A. \(CMS/CPC\)](#); [Corrigan, Dara \(HHS/OHR\)](#)
Subject: Fw: Draft Passback: Consumer Protection IFR
Date: Friday, June 18, 2010 12:30:09 PM
Importance: High

[Sent via Blackberry](#)

From: Aguilar, Brenda <Brenda_Aguilar@omb.eop.gov>
To: Aguilar, Brenda <Brenda_Aguilar@omb.eop.gov>; Cantwell, Kathleen (HHS) <kathleen.cantwell@hhs.gov>
Cc: Maguire, Daniel - EBSA; Turner, Amy - EBSA; Cosby, Chris - EBSA; Piacentini, Joseph - EBSA; Butikofer, James - EBSA; Mark.Iwry@do.treas.gov <Mark.Iwry@do.treas.gov>; George.Bostick@do.treas.gov <George.Bostick@do.treas.gov>; Weinheimer Russell E <Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV>; Widge, Alicia T. <Alicia_T._Widge@omb.eop.gov>; Fitzpatrick, Mary E. <Mary_E._Fitzpatrick@omb.eop.gov>; Malanoski, Margaret A. <Margaret_A._Malanoski@omb.eop.gov>; Helen.Morrison@do.treas.gov <Helen.Morrison@do.treas.gov>; Seshamani, Meena (HHS/ASPE) <Meena.Seshamani@hhs.gov>; Kronick, Richard (HHS/ASPE/HP) <Richard.Kronick@hhs.gov>; Sheingold, Steven (HHS/ASPE) <Steven.Sheingold@HHS.GOV>
Sent: Fri Jun 18 12:17:51 2010
Subject: RE: Draft Passback: Consumer Protection IFR

All – Using this as a general check in and follow-up.

1. Thanks so much for the responses to our comments on the NonRIA portions of the rule. Everyone was generally pleased with the changes (and even the non changes.) We did have one issue that we wanted to ask you all to explore further. We understand the time constraint and therefore if the 3 Departments are not comfortable with the suggestion, or believe that there is not sufficient time to develop consensus on it, we understand and it will not hold up our concluding review. It can be found at the bottom of the email.
2. We are also pleased with the portions of the RIA changes that we have seen. We find the responses reasonable and helpful and are unlikely to have further comment (hedging only because we still have parts missing and would like confirmation from the Departments that they are ok with our suggestions to the accounting statement/summary table.)
3. Checking in to see if you have any questions or concerns with the mortality discussion/insert that we provided this morning. Would be great if we could put that issue to bed now.
4. Quantitative benefit discussion. Understand that CEA has provided material. Wondering what the Departments' reaction is to it and the status of the revised summary benefits discussion.
5. Statement of need. We are anxious to see this and would be happy to review separately. Should be straightforward and another issue that could be quickly put to bed.

Please advise right away with any updates and especially concerns. And let me know if I got anything wrong or left something out.

Thanks,
Brenda

Non RIA Suggestion: In reference to comment b8 on p. 18 of non-RIA “Pkg of 4 Overview and Reg Text” document

This rescission prevention rule aims to prevent unjustified rescissions such as those stemming from clerical errors (e.g. typos for someone’s weight), errors created by other agents handling the form, or good faith mistakes by the patient. The current language aims to prevent these forms of unjustified rescissions by limiting rescissions to cases of “fraud” and “intentional misrepresentation of material fact.” However, the addition of “intentional” and “material fact” may not fully succeed in preventing unjustified rescissions. Under the current phrasing of the rule, it will still be relatively easy for insurers to legally justify continuing many rescission practices, as many patient omissions on forms can be shown to be “intentional” in the sense that they were omitted with the patient’s knowledge, even if there was no purpose on the part of the patient to mislead the insurer. In order to prevent such “gap” cases where rescissions are unjustified, but still would be permitted under the proposed rule, we suggest rephrasing the preamble and the regulatory text as outlined below. These suggestions aim to ensure that good faith errors by patients do not lead to unjustified rescissions, narrowing the scope of permissible rescissions to cases where the patient purposively misleads the insurer in bad faith.

Suggested Alternative 1:

Suggest refining current description of “fraud or intentional misrepresentation of material fact” in preamble and regulatory text in order to ensure sufficiently clarity to achieve the intended benefits of the rule.

- P. 18, last full sentence: rephrase (change in bold)
 - o “Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or **a bad faith misrepresentation of material fact intended to obscure information about the condition(s) for which the patient seeks treatment.**”
 - o Make parallel change to the same phrase in regulatory text on p. 49, p. 74, p. 98: (change/addition in bold)
 - ...unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes a **bad faith misrepresentation of material fact intended to obscure information about the condition(s) for which the patient seeks treatment, or intended to violate prohibitions in the terms of the plan or coverage.**”
- P. 18, after last full sentence, add the following:
 - o “These interim final regulations therefore understand bad faith intentional misrepresentation of material fact to exclude cases of clerical errors on patient forms, errors caused by other agents handling the form, or omissions resulting from good faith errors or misunderstandings by the patient.”

Suggested Alternative 2:

- P. 18, last full sentence: rephrase (change in bold)

- o “Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or **a bad faith**, intentional misrepresentation of material fact”
 - o Make parallel change to the same phrase in regulatory text on p. 49, p. 74, p. 98: (insertions in bold)
 - ...unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes a **bad faith and** intentional misrepresentation of material fact **that is** prohibited by the terms of the plan or coverage.”
- P. 18, after last full sentence, add the following:
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From: Aguilar, Brenda

Sent: Friday, June 18, 2010 9:42 AM

To: Aguilar, Brenda; 'Cantwell, Kathleen (HHS)'

Cc: 'Maguire.Daniel@dol.gov'; 'Turner, Amy - EBSA'; 'Cosby, Chris - EBSA'; 'Piacentini.Joseph@dol.gov'; 'butikofer.james@dol.gov'; 'Mark.Iwry@do.treas.gov'; 'George.Bostick@do.treas.gov'; 'Weinheimer Russell E'; Widge, Alicia T.; Fitzpatrick, Mary E.; Malanoski, Margaret A.; 'Helen.Morrison@do.treas.gov'; Seshamani, Meena (HHS/ASPE); Kronick, Richard (HHS/ASPE/HP); Sheingold, Steven (HHS/ASPE)

Subject: RE: Draft Passback: Consumer Protection IFR

All –

Please see attached for the Departments’ consideration is suggested language on the potential mortality benefits of the rulemaking. Please use and adapt as you see fit and let us know if you have questions or wish to discuss.

Thanks,
Brenda

From: Aguilar, Brenda

Sent: Thursday, June 17, 2010 7:02 PM

To: Aguilar, Brenda; 'Cantwell, Kathleen (HHS)'

Cc: 'Maguire.Daniel@dol.gov'; 'Turner, Amy - EBSA'; 'Cosby, Chris - EBSA'; 'Piacentini.Joseph@dol.gov'; 'butikofer.james@dol.gov'; 'Mark.Iwry@do.treas.gov'; 'George.Bostick@do.treas.gov'; 'Weinheimer Russell E'; Widge, Alicia T.; Fitzpatrick, Mary E.; Malanoski, Margaret A.

Subject: RE: Draft Passback: Consumer Protection IFR

All – per our earlier discussion, please see attached for our suggestions to revise the summary cost/benefit table.

Thanks so much for all your help. Please let us know if you have questions and feel free to tweak.

Brenda

From: Aguilar, Brenda

Sent: Thursday, June 17, 2010 10:52 AM

To: Cantwell, Kathleen (HHS)

Cc: Maguire.Daniel@dol.gov; Turner, Amy - EBSA; Cosby, Chris - EBSA; Piacentini.Joseph@dol.gov; butikofer.james@dol.gov; Mark.Iwry@do.treas.gov; George.Bostick@do.treas.gov; Weinheimer Russell E

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From: [CMS Coordination_Regs_OSORA](#)
To: [Mayhew, James A. \(CMS/CPC\)](#); [Small, Jacqueline C. \(CMS/OSORA\)](#); [Swann, Renee L. \(CMS/OEORA\)](#)
Subject: FW: Review and Clearance of OCIIIO-9994-IFC
Date: Wednesday, June 16, 2010 3:32:22 PM

From: Jones, Greg A. (CMS/OL)
Sent: Wednesday, June 16, 2010 3:27 PM
To: CMS Coordination_Regs_OSORA
Cc: Precht, Paul (CMS/OL); McWright, LAURA T. (CMS/OL); Massey, Beverly A. (CMS/OL); Harrison, Vernell M. (CMS/OL); Pettijohn, Juneous A. (CMS/OL)
Subject: RE: Review and Clearance of OCIIIO-9994-IFC

The OL C/D Group clears without comments.

From: CMS Coordination_Regs_OSORA
Sent: Wednesday, June 16, 2010 9:24 AM
To: CMS - Reg_Coordinators; CMS CMSO_REGS; Mayhew, James A. (CMS/CPC)
Cc: Parker, Lisa M. (CMS/OSORA); Swann, Renee L. (CMS/OSORA); Small, Jacqueline C. (CMS/OSORA)
Subject: Review and Clearance of OCIIIO-9994-IFC

OCIIIO-9994-IFC Interim Final Rules under the Patient Protection and Affordable Care Act Regarding Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Prohibition on Discrimination in Favor of the Highly Compensated, Patient Protections, and Non-Federal Governmental Plans

HEALTH CARE REFORM REGULATION

Clearance requested by 3:00 p.m. on June 16, 2010.

Urgency: This interim final rule is scheduled for publication on **June 21, 2010**. Therefore, it is important that we receive all clearances timely. Thank you, in advance, for your prompt response.

The subject document is attached for your review and clearance. If you are the regulations coordinator, please clear the document through all divisions in your center or office, even if your center or office is the lead policy component for the document. Please forward your responses to the **CMS Coordination_Regs_OSORA Outlook mailbox** by **3:00 p.m. on June 16, 2010**. Electronic markups should include redline and strikeouts of the additions and deletions by using the "Track Changes" feature in MS Word. If you are providing comments electronically, save your comments with your component's acronym in parentheses at the end of the file name (for example, if the component is CBC, then the file would be saved as 4069-P-Preamble(CBC).doc). It would also be helpful if you would suggest language that would respond to your comment to insert into the document.

Hard copy markups may be delivered to **Jackie Small (C5-10-25)**.

This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, prohibition on discrimination in favor of highly compensated individuals, patient protections, and non-federal governmental plans.

If you have any questions regarding submission of clearances and comments, you may contact **Jackie Small, x6-6538**. Please call **Jim Mayhew, x6-9244** for policy-related questions.

From: [Baum, Beth - EBSA](#)
To: [Turner, Amy - EBSA](#); [Lambrew, Jeanne \(HHS/OS/OHR\)](#); [Seshamani, Meena \(HHS/OHR\)](#); [Cosby, Chris - EBSA](#); [Mayhew, James A. \(CMS/CPC\)](#); [Corrigan, Dara \(HHS/OHR\)](#); [Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV](#); [Kosin, Donald \(HHS/OGC\)](#); [Knopf Kevin - OTP](#); [Kevin Knopf - HOME](#); [Levin Karen](#); [Elizabeth Schumacher](#); [Kronick, Richard \(HHS/ASPE/HP\)](#); [Sheingold, Steven \(HHS/ASPE\)](#); [Piacentini, Joseph - EBSA](#); [Butikofer, James - EBSA](#); [Cantwell, Kathleen \(HHS\)](#); [Taylor, William - SOL](#); [Maguire, Daniel - EBSA](#)
Cc: [Smalls, Dawn \(HHS/IOS\)](#); [Borzi, Phyllis - EBSA](#); [mark.iwry@do.treas.gov](#); [Childress, Mark \(HHS/OGC\)](#); [Michael M. Hash@who.eop.gov](#); [mhash@who.eop.gov](#); [Nancy-Ann M. DeParle@who.eop.gov](#); [Cass R. Sunstein@omb.eop.gov](#); [Aguilar, Brenda](#); [Malanoski, Margaret A.](#)
Subject: RE: 4-pack of consumer protections
Date: Sunday, June 20, 2010 3:39:51 PM
Attachments: [Pkg of 4 Omnibus 6 20 10 3pm clean with 230pm edits.doc](#)
Importance: High

Hi everyone -

Attached is an updated draft -- the only things marked in redline are the comments we went over on the 2:30 call, as well as the HHS PRA numbers (we sorted out our question with Margaret shortly after the call).

Per our conversation, we checked the link in footnote 16 on page 36 and it worked with the % symbols as used in the draft. It did not work when I took them out and tried spaces or underscores, so we left the link as it was.

Please review and let us know by 4:00pm if you have any problems with these changes. At that time, we will get the final document ready for printing, so we can get it to the Federal Register in the morning.

Thanks,
Beth

From: Turner, Amy - EBSA
Sent: Sunday, June 20, 2010 1:43 PM
To: 'Lambrew, Jeanne (HHS/ASPE)'; Seshamani, Meena (HHS/ASPE); Baum, Beth - EBSA; Cosby, Chris - EBSA; Mayhew, James A. (CMS/CPC); Corrigan, Dara (HHS/ASPE); Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV; Kosin, Donald (HHS/OGC); Knopf Kevin - OTP; Kevin Knopf - HOME; Levin Karen; Elizabeth Schumacher; Kronick, Richard (HHS/ASPE/HP); Sheingold, Steven (HHS/ASPE); Piacentini, Joseph - EBSA; Butikofer, James - EBSA; Cantwell, Kathleen (HHS); Taylor, William - SOL; Maguire, Daniel - EBSA; Turner, Amy - EBSA
Cc: Smalls, Dawn (HHS/IOS); Borzi, Phyllis - EBSA; mark.iwry@do.treas.gov; Childress, Mark (HHS/OGC); Michael M. Hash@who.eop.gov; mhash@who.eop.gov; 'Nancy-Ann M. DeParle@who.eop.gov'; 'Cass R. Sunstein@omb.eop.gov'; Aguilar, Brenda; 'Malanoski, Margaret A.'
Subject: RE: 4-pack of consumer protections

Per the email below, attached is the current document. Thanks very much to Beth for all her hard work putting this together under a very difficult timeline!!

From: Lambrew, Jeanne (HHS/ASPE) [mailto:Jeanne.Lambrew@hhs.gov]
Sent: Sunday, June 20, 2010 11:51 AM
To: Turner, Amy - EBSA; Seshamani, Meena (HHS/ASPE); Baum, Beth - EBSA; Cosby, Chris - EBSA; Mayhew, James A. (CMS/CPC); Corrigan, Dara (HHS/ASPE); Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV; Kosin, Donald (HHS/OGC); Knopf Kevin - OTP; Kevin Knopf - HOME; Levin Karen; Elizabeth Schumacher; Kronick, Richard (HHS/ASPE/HP); Sheingold, Steven (HHS/ASPE); Piacentini, Joseph - EBSA; Butikofer, James - EBSA; Cantwell, Kathleen (HHS); Taylor, William - SOL; Maguire, Daniel - EBSA
Cc: Smalls, Dawn (HHS/IOS); Borzi, Phyllis - EBSA; mark.iwry@do.treas.gov; Childress, Mark

(HHS/OGC); Michael_M._Hash@who.eop.gov; mhash@who.eop.gov

Subject: RE: 4-pack of consumer protections

Thanks all.

On a separate email with Cass, Phyllis, Mark, Nancy-Ann and Cass and Mark and I decided on a modified process.

Comments still due by 1pm.

Amy, could you our Beth can incorporate those comments into one document by 1:30? This redline document should be sent out to this group plus Nancy-Ann, Cass, Margaret and Brenda from OMB.

At 2:30, we'll have a conference call to finalize the document. We'll use:

1-877-972-1957

x 398 1952

After that, if there are any changes, it will be recirculated for final sign off by 4pm-ish.

Cass agreed -- no need to go back through ROCIS: We'll use this process instead.

Sincere apologies for the weekend work, especially to those fathers on the email. But this work matters to many more fathers, mothers, kids, etc than are on this email chain: if they knew you all worked so hard to make this right, they would be half as grateful as we are for your work.

From: Turner, Amy - EBSA [mailto:Turner.Amy@dol.gov]

Sent: Sun 6/20/2010 10:36 AM

To: Turner, Amy - EBSA; Seshamani, Meena (HHS/ASPE); Baum, Beth - EBSA; Cosby, Chris - EBSA; Mayhew, James A. (CMS/CPC); Corrigan, Dara (HHS/ASPE); Russell.E.Weinheimer@IRSCOUNSEL.TREAS.GOV; Kosin, Donald (HHS/OGC); Knopf Kevin - OTP; Kevin Knopf - HOME; Levin Karen; Elizabeth Schumacher; Kronick, Richard (HHS/ASPE/HP); Sheingold, Steven (HHS/ASPE); Piacentini, Joseph - EBSA; Butikofer, James - EBSA; Cantwell, Kathleen (HHS); Taylor, William - SOL; Maguire, Daniel - EBSA

Cc: Smalls, Dawn (HHS/IOS); Borzi, Phyllis - EBSA; mark.iwry@do.treas.gov; Lambrew, Jeanne (HHS/ASPE); Childress, Mark (HHS/OGC); Michael_M._Hash@who.eop.gov

Subject: 4-pack of consumer protections

All, See attached and below. We believe that the attached draft incorporates all the comments we've received this weekend, including those from Nancy-Ann. Please review and advise if you have any concerns. Also, a few issues are highlighted in the email below (which references the attached email from Chris Cosby). We would like to resolve any remaining comments and issues by 1PM today. If we need to, we will arrange a 2PM conference call to resolve remaining items. The plan is to ROCIS a clean version of the final document by 3PM today.

Thanks to everyone for coming together on this, even on Father's Day!!

From: Baum, Beth - EBSA

Sent: Sunday, June 20, 2010 10:29 AM

To: Turner, Amy - EBSA

Subject: Current Markup of the 4-Pack

Amy -

Attached is the current markup that includes everyone's comments since Friday night.

Take a look at the edits (and a few issues I am highlighting in this email).

1. Pg 68 - there is a sentence about enforcement authority with respect to rescissions. We are running this sentence by Bill Taylor in our solicitor's office to make sure he is comfortable with it, but you may want to take a look.

2 . HHS paperwork issue -- there were several emails Friday night about this. The document indicates that there should be 3 HHS PRA numbers (one for lifetime limits, one for rescissions, and one for patient protections), just like there are 3 PRA numbers each for DOL and IRS. Maybe we can ask Kathleen to check with Brenda on this? The relevant pages in this document are 113, 115, and 117. We will also need the dates to fill in for the HHS signature page , so we'll need to ask someone what those dates should be.

3. Pg. 84 - Meena had a comment on this, and I think you resolved it this morning with your edits.

4. Outstanding issues from Chris Cosby's email yesterday -- he had a few unresolved issues that he indicated the HHS economists should check out: I am attaching his email as well.

If we need to have a call, I can circulate the conference line info.

Thanks,
Beth